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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Michael A. Apicella et al.	Examiner: Yong Pak
Serial No.:	09/574,460	Group Art Unit: 1652
Filed:	May 18, 2000	Docket: 875.009US1
Title:	PRODUCTION OF COMPLEX CARBOHYDRATES	

DECLARATION OF DR. APICELLA UNDER 37 C.F.R. § 1.132

1. I, Michael Apicella, am one of the co-inventors of the above-identified patent application and am currently a tenured Professor and Chairman of Department of Microbiology at The University of Iowa in Iowa City, Iowa. I have held that position for seven years. I began my scientific career at Johns Hopkins University in 1966 and since that time have been a faculty member of the State University of New York at Buffalo and The University of Nevada, Reno. I obtained my M.D. degree from the State University of New York in Brooklyn in 1963. I have worked in the area of Bacterial pathogenesis and genetics for the past 30 years after completing my post-doctoral fellowship at Johns Hopkins School of Medicine. I have published over 140 articles in peer reviewed scientific journals in these areas since that time. As mentioned above, I have collaborated with Dr. Bradford Gibson for over 10 years on the structure analysis and biology of compounds produced by numerous pathogenic and non-pathogenic bacteria including *Haemophilus*, *Neisseria*, *Salmonella*, *E. coli* and *Moraxella*.

2. In order to determine if the *Haemophilus influenzae lsg* locus could be used to produce chimeric LPS structure in Gram-negative bacteria other than *E. coli*, the *Salmonella minnesota* Ra strain 1112 mutant was transformed with the plasmid pGEM and pGEMLOS-4. *S. minnesota* Ra strain 1112 contains the entire core region of this LPS and lacks any O-antigen structures. The plasmid pGEM does not contain any genetic insertion in its multicloning site while pGEMLOS-4 contains the complete 7.2 kb *lsg* in the multicloning site. Figure 1 shows the results of a silver stained SDS-PAGE gel demonstrating the addition of a 1.4 kDa addition to the *S. minnesota* Ra strain 1112 LPS by the *lsg* locus. Figure 2 shows the results of a colony lift immunoblots of the *S. minnesota* Ra strain 1112 strains containing pGEM and pGEMLOS4 using monoclonal antibody 6E4 which recognizes a terminal epitope present on all *H. influenzae* lipooligosaccharide. As can be seen, colonies of *S. minnesota* Ra strain 1112 containing

pGEMLOS-4 expressed this epitope while those of *S. minnesota* Ra strain 1112 with the plasmid alone did not express this epitope. These studies demonstrate that Gram negative bacteria other than *E. coli* can be used to make complex carbohydrates with the *lsg* locus.

Figure legends: Figure 1 is a silver stained SDS-PAGE showing the differences in the LPS's of *S. minnesota* Ra strain 1112 (lane A), *S. minnesota* Ra strain 1112 pGEMLOS-4 (lane B) and *S. minnesota* Ra strain 1112 pGem (lane C). As can be seen a 1.4 kDa addition is present on the *S. minnesota* Ra strain 1112 pGEMLOS-4 LPS.

Figure 2 are two colony immunoblots develop with monoclonal antibody 6E4, which recognizes a conserved structure on *H. influenzae* LOS. Panel A shows an immunoblot of *S. minnesota* Ra strain 1112 pGem colonies while panel B shows an immunoblot of *S. minnesota* Ra strain 1112 pGEMLOS-4 colonies (solid arrows) with monoclonal 6E4 . A positive control of *H. influenzae* A2 LOS is shown by the dotted arrows.

3. I am a co-author of Kwaik *et al.*, *Molecular Microbiology* 5(10), 2475-2480 (1991). This paper focused on the identification of a set of genes that encoded glycosyltransferases. At the time of the paper we had no evidence that components of *H. influenzae lsg* locus could control *E. coli* genes. We had no evidence that increased expression of *E. coli rfe* was related to its control by *H. influenzae lsgG.* We had no evidence that the chimeric carbohydrate was assembled on a terminal heptose on the *E. coli* K12 strain. We had no evidence that the structure of the chimeric LPS resulted in a di-lactosamine structure emanating from a terminal heptose on the *E. coli* core. The elucidation of the mechanism by which this chimeric structure was assembled was elucidated over the next eight years and resulted in the present specification.

4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that the statements are made with the knowledge that willful false statement and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States

Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

11/06/01
Date

Michael Apicella

Figure 1

A = *S. minnesota* Ra LPS

B = *S. minnesota* Ra pGEMLOS-4 LPS

C = *S. minnesota* Ra pGEM LPS

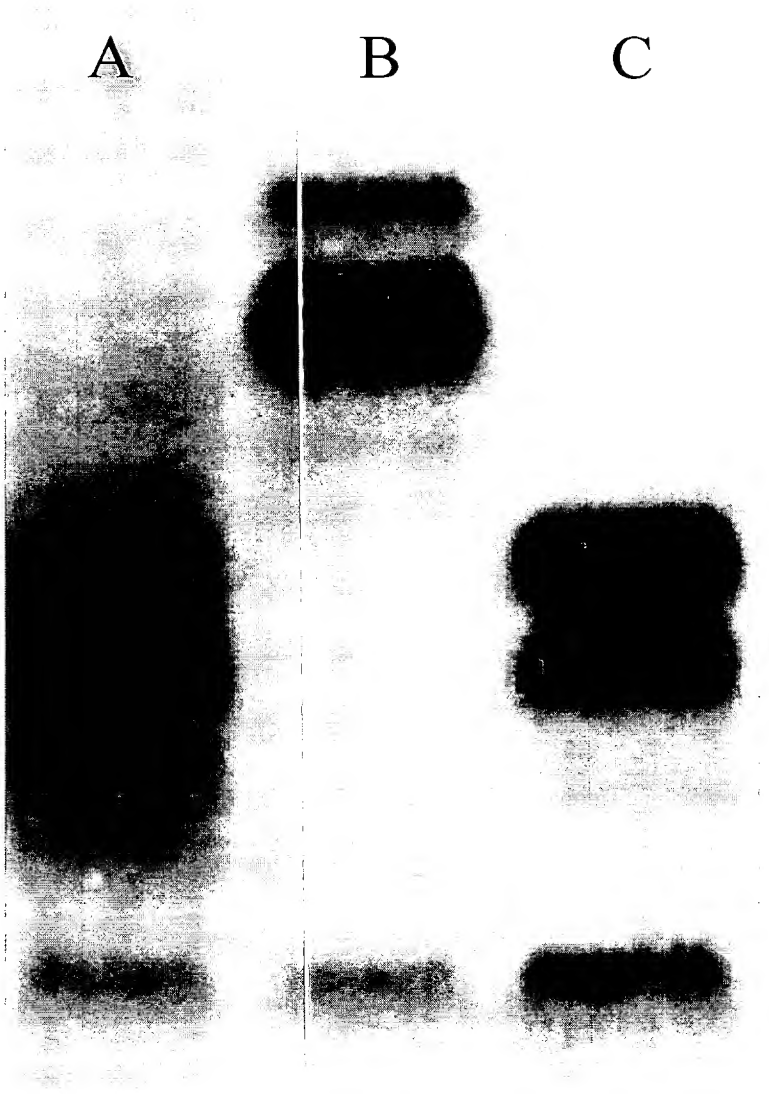
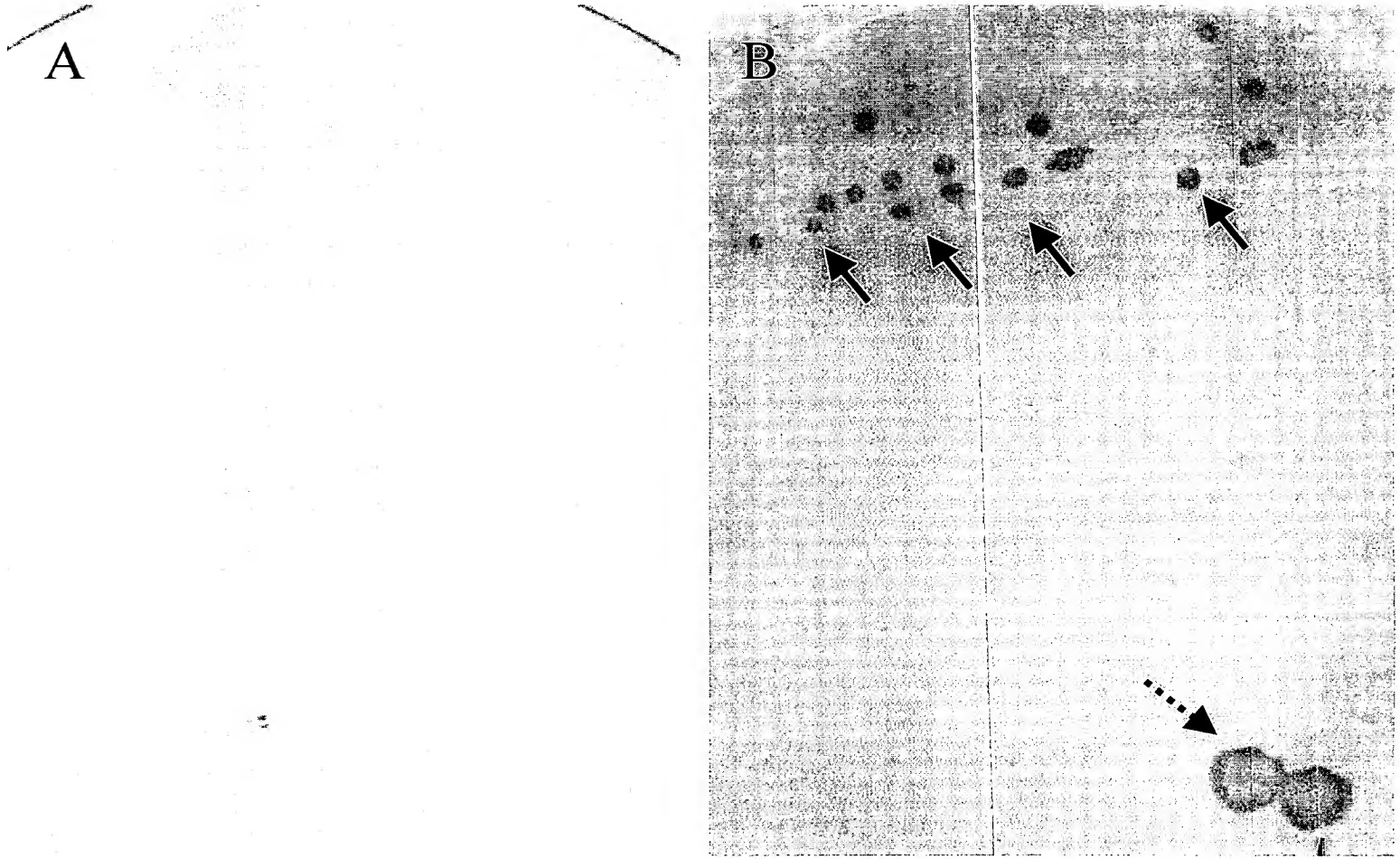


Figure 2



Decisions of the United States Courts and of the United States Patent and Trademark Office in Patent, Trademark, and Copyright Cases

U.S. Court of Appeals
Federal Circuit

Genentech Inc. v. Novo Nordisk A/S

No. 96-1440

Decided March 13, 1997

PATENTS

1. Patentability/Validity — Specification — Enablement (§115.1105)

Specification of patent in suit would not have enabled person of ordinary skill in art at time of filing to use cleavable fusion expression to make human growth hormone without undue experimentation, since specification merely describes three or four applications for which cleavable fusion expression is generally well-suited, and names enzyme that might be used as cleavage agent as well as sites at which it cleaves, and thus does not describe specific material to be cleaved or any reaction conditions under which cleavable fusion expression would work, and since evidence does not support patentee's contention that disclosure of DNA encoding hGH, combined with prior art cleavable fusion expression techniques applied to non-human proteins, would enable practice of claimed method.

2. Patentability/Validity — Specification — Enablement (§115.1105)

Rule that specification need not disclose what is well known in art means only that omission of minor details does not cause specification to fail to meet enablement requirement, and is not substitute for basic enabling disclosure; if there is no disclosure of any starting material or of any conditions under which claimed process can be carried out, undue experimentation is required, and there is failure to meet enablement requirement that cannot be rectified by asserting that all disclosure related to process is within skill of art.

3. Patentability/Validity — Specification — Enablement (§115.1105)

Specification that states problem of obtaining human growth hormone from precursor containing added protein material does not enable claim for method of producing hGH using cleavable fusion expression, since specification discloses method in which problem is solved by obtaining hGH unaccompanied by leader sequence or other extraneous proteins, but does not provide specific enabling disclosure for obtaining hGH by cleaving hGH-containing protein as recited in claim.

4. Patentability/Validity — Specification — Enablement (§115.1105)

Fact that no one had been able to produce any human protein via cleavable fusion expression as of application date of patent in suit undermines patentee's contention that specification's disclosure of DNA sequence encoding human growth hormone and single example enzyme and its cleavage site, without more, would have enabled one skilled in art to have used claimed cleavable fusion expression method to make hGH without undue experimentation; moreover, if disclosure of useful conjugate protein and method for its cleavage were clearly within skill of art, as patentee asserts, it would have been expressly disclosed in specification, and in customary detail.

Particular patents — Chemical — Human growth hormone

5,424,199, Goeddel and Heyneker, human growth hormone, invalid for lack of enablement.

Appeal from the U.S. District Court for the Southern District of New York, Motley, J.

Action by Genentech Inc. against Novo Nordisk A/S, Novo Nordisk of North America Inc., and Novo Nordisk Pharmaceuticals Inc. for patent infringement. From grant of plaintiff's motion for preliminary injunction, defendants appeal. Injunction vacated; patent held invalid as matter of law for failure of specification to enable practice of claimed method.

Prior decision: 37 USPQ2d 1773.

Leora Ben-Ami, John E. Kidd, Nicholas L. Coch, Joseph Ferraro, Philip E. Roux, and Gerard P. Norton, of Rogers & Wells, New York, N.Y.; Ryan Trainer, of Rogers & Wells, Washington, D.C., for plaintiff-appellee.

Albert L. Jacobs Jr., Jesse D. Reingold, Gerard F. Diebner, Daniel A. Ladow, Brad S. Needleman, and Andrew T. Solomon, of Graham & James, New York; John C. Vassil, Kurt E. Richter, and Kenneth H. Sonnenfeld, of Morgan & Finnegan, New York, for defendants-appellants.

Before Archer chief judge, and Lourie and Bryson, circuit judges.

Lourie, J.

Novo Nordisk A/S, Novo Nordisk of North America, Inc., and Novo Nordisk Pharmaceuticals, Inc. (collectively "Novo") appeal from the order of the United States District Court for the Southern District of New York, issuing a preliminary injunction in favor of Genentech, Inc., enjoining Novo from importing, marketing, using, selling, offering for sale or distributing its Norditropin®-brand recombinant human growth hormone (hGH) product. *Genentech, Inc. v. Novo Nordisk A/S*, 935 F. Supp. 260 (S.D.N.Y. 1996). Because the district court's conclusion that Genentech had demonstrated a likelihood of success on the merits was based on an error of law and because its remaining findings were premised on this error, we vacate the injunction.

BACKGROUND

This consolidated patent infringement action was first brought in the United States District Court for the Southern District of New York on November 30, 1994. On May 12, 1995, Genentech moved for a preliminary injunction under U.S. Patent 4,601,980 to prevent Novo from importing, marketing, using, selling, offering for sale or distributing in the United States its Norditropin®-brand recombinant hGH product. The district court granted Genentech's motion and issued an injunction. *Novo Nordisk of North Am., Inc. v. Genentech, Inc.*, No. 94 Civ. 8634 (CBM), 1995 U.S. Dist. LEXIS 12588, 1995 WL 512171 (S.D.N.Y. Aug. 28, 1995).

On appeal this court vacated the injunction. *Novo Nordisk of North Am., Inc. v. Genentech, Inc.*, 77 F.3d 1364, 37 USPQ2d 1773 (Fed. Cir. 1996). We held that the district court clearly erred in finding that Genentech established a likelihood of proving infringement of the '980 patent because that finding was based on an improper construction of claim 2 of the patent. Based upon the specification and prosecution history, we concluded that because the claim used the phrase "human growth hormone unaccompanied by . . . other extraneous protein," it was limited to processes for directly expressing either hGH or met-hGH. *Id.* at 1371, 37 USPQ2d at 1779. Because the parties agreed that Novo did not use direct expression to produce these proteins, we concluded that Novo did not infringe the patent. *Id.*

Upon returning to the district court, Genentech asserted its newly issued U.S. Patent 5,424,199. The '199 patent has the same specification as the '980 patent and contains a single claim directed to:

> [a] method of producing a protein consisting essentially of amino acids 1-191 of human growth hormone comprising:
>
> (a) expressing in a transformant bacterium, DNA coding for a human growth hormone conjugate protein, which conjugate protein consists essentially of amino acids 1-191 of human growth hormone as set forth in combined Figs. 1 and 3 unaccompanied by the leader sequence of human growth hormone or other extraneous protein bound thereto and an additional amino acid sequence which is specifically cleavable by enzymatic action, and
>
> (b) cleaving extracellularly said conjugate protein by enzymatic action to produce said protein consisting essentially of amino acids 1-191 of human growth hormone.

This claim differs from the claim adjudicated in the prior case in reciting that the encoded protein has an additional amino acid sequence and includes the step of cleaving this conjugate protein. This process of expressing a DNA encoding a conjugate protein and using an enzyme to cleave off an undesired portion of that protein is generally known as cleavable fusion expression. The parties agree that Novo uses cleavable fusion expression to produce hGH. *Id.*

On June 27, 1996, after conducting a twelve-day evidentiary hearing, the district court again issued a preliminary injunction, this time based upon the '199 patent, enjoining Novo from importing, marketing, using, selling, offering for sale, or distributing in the United States its Norditropin®-brand recombinant hGH product. *Genentech v. Novo Nordisk A/S*, 935 F. Supp. 260 (S.D.N.Y. 1996). The district court based its decision upon, *inter alia*, a finding that Genentech would likely overcome Novo's defense that the '199 patent was invalid for lack of an enabling disclosure under 35 U.S.C. § 112, ¶ 1 (1994).

Novo appeals to this court, challenging the grant of the preliminary injunction.[1] We have jurisdiction pursuant to 28 U.S.C. § 1292 (c) (1994).

DISCUSSION

The grant or denial of a preliminary injunction pursuant to 35 U.S.C. § 283 is within the discretion of a district court. *We Care, Inc. v. Ultra-Mark Int'l Corp.*, 930 F.2d 1567, 1570, 18 USPQ2d 1562, 1564 (Fed. Cir. 1991). Accordingly, a trial court's decision granting a preliminary injunction will be overturned on appeal only upon a showing that the court abused its discretion. *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 772, 28 USPQ2d 1378, 1380 (Fed. Cir. 1993). Such an abuse of discretion may be established by showing that the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings. *Id.*

As the moving party, Genentech had to establish its right to a preliminary injunction in light of four factors: (1) a reasonable likelihood of success on the merits; (2) irreparable harm if the injunction were not granted; (3) the balance of the hardships; and (4) the impact of the injunction on the public interest. *Nutrition 21 v. United States*, 930 F.2d 867, 869, 18 USPQ2d 1347, 1348-49 (Fed. Cir. 1991); *Hybritech Inc. v. Abbott Lab.*, 849 F.2d 1446, 1451, 7 USPQ2d 1191, 1195 (Fed. Cir. 1988).

A. *Likelihood of Success on the Merits*

In order to demonstrate that it has a likelihood of success, Genentech must show that, in light of the presumptions and burdens that will inhere at trial on the merits, (1) it will likely prove that Novo infringes the '199 patent and (2) its infringement claim will likely withstand Novo's challenges to the validity and enforceability of the '199 patent. *See New England Braiding Co. v. A.W. Chesterton Co.*, 970 F.2d 878, 882-83, 23 USPQ2d 1622, 1625-26 (Fed. Cir. 1992).[2] In other words, if Novo raises a "substantial question" concerning validity, enforceability, or infringement (*i.e.*, asserts a defense that Genentech cannot show "lacks substantial merit") the preliminary injunction should not issue. *Id.* More specifically, with regard to Novo's validity defenses, the question on appeal is whether there is substantial merit to Novo's assertion that the '199 patent claim fails to meet the requirements of 35 U.S.C. § 112, ¶ 1 (1994).

Novo argues that the district court's findings regarding validity under § 112, ¶ 1, are clearly erroneous because it presented clear and convincing evidence that the patent specification would not have enabled a person of ordinary skill in the art to practice the claimed invention without undue experimentation. Novo also argues that the specification fails to contain a written description of the claimed invention. Regarding enablement, Novo argues that the patent is invalid because it does not contain sufficient detail concerning the practice of the claimed method. Novo argues that the mere generic statement of the possibility of cleavable fusion

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[1] On July 3, Novo moved for an emergency stay of the injunction pending disposition of this appeal. On August 1, we denied Novo's motion and reinstated the injunction. However, after having heard oral argument in this case, we reconsidered the motion and reinstated the stay of the injunction.

[2] A patent is presumed valid, 35 U.S.C. § 282 (1994), and a party challenging validity must prove invalidity by clear and convincing evidence. "However, the presumption does not relieve a patentee who moves for preliminary injunction from carrying the normal burden of demonstrating that it will likely succeed on all disputed liability issues at trial, even when the issue concerns the patent's validity." *New England Braiding*, 970 F.2d at 882, 23 USPQ2d at 1625 (citing *Nutrition 21*, 930 F.2d at 869, 18 USPQ2d at 1349).

expression, along with the DNA sequence encoding hGH, a single enzyme (trypsin) for cleaving undisclosed conjugate proteins, and a statement of that enzyme's cleavage sites as being potential amino acid extensions conjugated to hGH is not an enabling disclosure commensurate in scope with the claim. Genentech responds that all of the district court's factual findings regarding enablement are supported by the record. More specifically, Genentech argues that those skilled in the art of recombinant protein expression and purification at the time of filing, July 5, 1979, would have been able to use cleavable fusion expression to produce hGH without undue experimentation by using the teachings of the specification along with methods and tools well known in the art. We conclude that Novo has raised more than a substantial question concerning the validity of the '199 patent. In fact, it has shown that the patent is invalid.

Section § 112, ¶ 1, provides, in relevant part that:

> [t]he specification shall contain a written description of the invention, and the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .

"[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) ("[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art."). Whether making and using the invention would have required undue experimentation, and thus whether the disclosure is enabling, is a legal conclusion based upon several underlying factual inquiries. *See In re Wands*, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988).

[1] The question before us is whether the specification would have enabled a person having ordinary skill in the art at the time of filing to use cleavable fusion expression to make hGH without undue experimentation. There is no dispute that the portion of the specification chiefly relied upon by Genentech and by the district court, column 7, lines 29-59, does not describe in any detail whatsoever how to make hGH using cleavable fusion expression. For example, no reaction conditions for the steps needed to produce hGH are provided; no description of any specific cleavable conjugate protein appears. The relevant portion of the specification merely describes three (or perhaps four) applications for which cleavable fusion expression is *generally* well-suited and then names an enzyme that might be used as a cleavage agent (trypsin), along with sites at which it cleaves ("arg-arg or lys-lys, etc.").[3] Thus, the specification does not describe a specific material to be cleaved or any reaction conditions under which cleavable fusion expression would work.

Notwithstanding this limited disclosure, Genentech argues (and the district court found) that those of ordinary skill in the art would have been able to practice the claimed invention without undue experimentation. Essentially, Genentech's argument is that the knowledge of one skilled in the art was sufficient to provide all of the missing information and, more specifically, that the disclosure of a DNA encoding hGH, when combined with prior art cleavable fusion expression techniques applied to non-human proteins, would enable the practice of the claimed method. In support of this argument, Genentech points to the testimony of Dr. Ravetch, who testified as to the knowledge of one skilled in the art, to the extensive description of enzymes in the reference textbook *Methods in Enzymology*, and to the specification's explicit reference to British Patent 2008123-A, which more fully details the potential use of trypsin in cleavable fusion expression.

In response to these arguments, Novo asserts that at the time of filing, trypsin and other like enzymes were used only to digest proteins, not to specifically and precisely cleave conjugate proteins to yield intact, useful proteins, and that the British patent explicitly indicates that trypsin would not be useful for the cleavable fusion expression of arginine-containing proteins such as hGH. Novo further argues that neither the specification nor the references cited by Genentech suggest a single amino acid sequence, out of the virtually infinite range of possibilities,

[3] At column 7, lines 52-58, the specification states: "At least in the latter three applications [of the four applications that are disclosed], the synthetic adaptor molecular [sic] employed to complete the coding sequence of the mRNA transcript can additionally incorporate codons for amino acid sequences specifically cleavable, as by enzymatic action. For example, trypsin will cleave specifically at arg-arg or lys-lys, etc."

that would yield hGH in a useful form when cleaved from the conjugate protein.

We agree with Novo. Genentech's arguments, focused almost exclusively on the level of skill in the art, ignore the essence of the enablement requirement. Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. That requirement has not been met in this specification with respect to the cleavable fusion expression of hGH.

[2] It is true, as Genentech argues, that a specification need not disclose what is well known in the art. *See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research.

[3] The specification indicates that it purports to solve a problem. That problem is summarized at column 3, line 65, through column 4, line 8:

> [A] need has existed for new methods of producing hGH and other polypeptide products in quantity and that need has been particularly acute in the case of polypeptides too large to admit to organic synthesis or, for that matter, microbial expression from entirely synthetic genes. Expression of mammalian hormones from mRNA transcripts . . . has permitted only microbial production of bio-inactive conjugates from which the desired hormone could not practically be cleaved.

The problem thus was the difficulty of obtaining hGH from a precursor containing added protein material. This problem was solved by the description of a method of obtaining hGH unaccompanied by a leader sequence or other extraneous proteins, as claimed in the '980 patent. However, the specification for the '199 patent, which is the same as the specification for the '980 patent, does not provide a specific enabling disclosure concerning what the new claim recites, *viz.*, obtaining hGH by cleaving an hGH-containing conjugate protein. That was the problem avoided by the invention claimed in the '980 patent. The present specification contains no more disclosure than the '980 specification, but this patent now purports to claim the unresolved problem that the '980 patent overcame. Genentech is attempting to bootstrap a vague statement of a problem into an enabling disclosure sufficient to dominate someone else's solution of the problem. This it cannot do.

Genentech's arguments in favor of enablement are unavailing. While Genentech's witness, Dr. Ravetch, did state that it would have been possible for a skilled artisan to create a DNA sequence coding for arg-arg-hGH or lys-lys-hGH, he did not discuss the experimentation needed for the creation of DNA coding for more extensive sequences, such as those that have proved necessary to the production of hGH via cleavable fusion expression. Likewise, the description of a wide range of enzymes in *Methods in Enzymology*, by itself, does not render routine the determination of an enzyme-conjugate protein combination. Rather, as Novo argues and the record reflects, various combinations of conjugate protein sequences, cleaving enzymes, and reaction conditions needed to be studied to establish a process for producing hGH in useful form. Finally, the British patent cited in the specification actually works against Genentech's position by explicitly teaching that trypsin would not work well to produce hGH. The specification does not even acknowledge any of the known difficulties associated with using trypsin on an hGH conjugate protein. This specification is so lacking with respect to the limitation of paragraph (b) of claim 1 that providing testimony regarding the skill in the art has been an exercise in futility.

[4] The limited testimony regarding the knowledge of one skilled in the art offered by

Genentech at the preliminary injunction hearing, and relied upon by the district court, is further undermined by the fact that no one had been able to produce *any* human protein via cleavable fusion expression as of the application date. If, as Genentech argues, one skilled in the art, armed only with what the patent specification discloses (a DNA sequence encoding a human protein, in this case, hGH, and a single example of an enzyme and its cleavage site), could have used cleavable fusion expression to make a human protein without undue experimentation, it is remarkable that this method was not used to make any human protein for nearly a year, *see* Shine *et al.*, 285 Nature 456 (June 1980), or to make hGH for five years. *See* Belagaje *et al.*, 3 DNA 120 (1984). Certainly, DNAs encoding desirable human proteins were known at the time of filing (*e.g.*, insulin, described in the British patent), and a great many researchers were attempting to produce human proteins using recombinant DNA technology. This failure of skilled scientists, who were supplied with the teachings that Genentech asserts were sufficient and who were clearly motivated to produce human proteins, indicates that producing hGH via cleavable fusion expression was not then within the skill of the art. The contrary testimony offered by Genentech's witnesses, who hypothesized about the skill of the art more than fifteen years earlier, does not demonstrate the incorrectness of Novo's arguments. *See In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991) ("[A]n expert's opinion on the ultimate legal issue [of enablement] must be supported by something more than a conclusory statement.").

Moreover, it stands to reason that if the disclosure of a useful conjugate protein and the method for its cleavage were so clearly within the skill of the art, it would have been expressly disclosed in the specification, and in the usual detail. Patent draftsmen are not loath to provide actual or constructive examples, with details, concerning how to make what they wish to claim. In addition, as indicated above, the specification of this patent was clearly drafted to claim the invention of obtaining hGH *unaccompanied by* extraneous protein, the cleavage of which was identified by the specification as a problem in this field. Genentech's inventors knew how to enable that which they had invented. These facts underline the inadequacy of the specification in enabling that which it provided only a means to avoid.

The record does not support the district court's implicit finding that the disclosure of trypsin and its cleavage site enables the production of any conjugate protein from which hGH can practically be cleaved and thus produced in useful form; the record indicates that determination of these features required further undue experimentation. None of the expert testimony relied upon by Genentech or by the district court suggests otherwise.[4] Where, as here, the claimed invention is the application of an unpredictable technology in the early stages of development, an enabling description in the specification must provide those skilled in the art with a specific and useful teaching. Genentech has not shown that the '199 patent provides that teaching.

Under the circumstances, we are compelled to conclude that the district court made an error of law in ruling that Genentech showed a likelihood of success on enablement. *See In re Epstein*, 32 F.3d 1559, 1568, 31 USPQ2d 1817, 1823 (Fed. Cir. 1994) ("[E]nablement is a question of law . . . which may involve subsidiary questions of fact."). Furthermore, since we are able to review the record and to read the specification, there is no reason why we should limit our decision here to reversing the grant of the preliminary injunction. Rather, because the parties agreed at oral argument that the enablement issue had been thoroughly ventilated by the extensive arguments before the district court and that court's extensive analysis,[5] we deem it appropriate to rule on the merits of Novo's defense of invalidity *See* 28 U.S.C. § 2106 (1994) ("The Supreme Court or any other court of appellate jurisdiction may . . . direct the entry of such appropriate judgment, decree, or order, or require such further proceedings to be had as may be just under the circumstances."); *Chicago Observer, Inc. v. City of Chicago*, 929 F.2d 325, 329 (7th Cir. 1991) (reversing preliminary injunction and instructing district court to enter judgment in favor of defendant because the plaintiff "has not suggested that it holds more evidence it could offer at trial and we cannot imagine what additional evidence could aid its cause. Litigation is costly not only for the litigants but also for parties in other cases waiting in the queue for judicial attention. Once it becomes clear that additional proceedings are pointless, the court should bring the case to a close."). We therefore hold that claim 1 and hence the '199 patent are invalid as a matter of law for failure of the specification to enable the practice of the claimed method.

Novo has also argued that the '199 patent is invalid for lack of a written description of the claimed invention and that it is not infringed by Novo. Given our decision on the enablement question, we need not reach these issues.

B. *Other Factors*

Novo also challenges the district court's findings that irreparable harm, the equities, and the public interest favored Genentech. In view of our conclusion concerning the invalidity of the '199 patent, we need not consider these other findings.

CONCLUSION

The court abused its discretion by granting the preliminary injunction based upon an error of law. The district court's error was in finding that Genentech had shown a likelihood of success on the merits since the '199 patent is invalid for failure of the specification to meet the enablement requirement of § 112, ¶ 1. Accordingly, we vacate the injunction and instruct the district court to dismiss Genentech's claim for infringement of the '199 patent on the ground that the patent is invalid.

VACATED.

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[4] Novo's witness, Dr. Villa-Komaroff, merely stated on cross-examination that, assuming arg-arg-hGH was initially produced and successfully extracted from the transformed cell, that "[u]nder the best condition, approximately five percent of the time there will be in the [post-digestion] mix [hGH]." This statement, characterized by Genentech as an admission, was made in the limited context of partial trypsin digests of isolated arg-arg-hGH, but none of the necessary experimentation is described in the specification, which is where it should be if it is to contribute to an enabling disclosure.

[5] Genentech stated that it would introduce new evidence at a full trial only in response to new arguments and new defenses raised by Novo. Novo revealed that it had no intention of raising any new arguments or defenses, stating that the "full and complete record" on appeal gave this court "the benefit of everything it really needs" to reach ultimate issues of validity. Thus, considerations that would normally dictate that we limit our decision to reversing the grant of the preliminary injunction are not present. *See University of Texas v. Camenisch*, 451 U.S. 390, 395 (1981) (stating that it is generally inappropriate to render a final judgment on the merits at the preliminary injunction stage because "a preliminary injunction is customarily granted on the basis of procedures that are less formal and *evidence that is less complete than in a trial on the merits.*") (citations omitted) (emphasis added).

U.S. District Court
District of Columbia

U.S. v. The Thomson Corp.

No. 96-1415 (PLF)

Decided December 23, 1996

COPYRIGHTS

1. Elements of copyright — Statutory Elements — Originality (§205.0707)

Legal publisher asserting copyright in "star pagination" of its case law reporters has "thin" copyright claim at best, since in order to prevail, publisher would have to demonstrate that its reporter page numbers and their placement themselves represent original, creative decision about selection or arrangement, since where and on what pages text of court opinion appears does not embody any original creation of compiler, and since star pagination does not in any way take advantage of that part of publisher's effort in making compilation that reflects its intellectual effort, and instead simply reflects accident of where particular portion of opinion ended up in reporter.

2. Rights in copyright; infringement — Ownership of copyright — Transfer and licensing (§213.0310)

Provision in proposed final judgment in antitrust action, by which two legal publishing companies, as condition of their merger, would be required to grant license for fee to anyone who wants to "star paginate" to case law reporter system, is not in public interest as required by Antitrust Procedures and Penalties Act, 15 USC 16, since copyrightability of star pagination is questionable at best, since including star pagination license in final judgment might be construed as government's endorsement of publishers' dubious copyright claim, since provision would legitimize publishers' ability to profit from licenses while copyright issue is litigated, and since that fact alone is troublesome in view of weakness of copyright claim and limited market power of many of those who would have to pay license fee.

Action brought under federal antitrust laws by the United States and by states of California, Connecticut, Illinois, Massachu-

Cir. 1988) (*en banc*), *cert. denied*, 490 U.S. 1067 (1989).

The ALJ had criticized Modine's choice of the data that were included in the grandparent application as filed, for Modine had replaced a graph of computer-generated heat transfer data, that appeared in an early draft of the patent application, with later-obtained data and comparison with a different prior art condenser. Modine explained at trial the flaws in the first set of data, and the reasons for the change to data that were believed to be more accurate and to present a more useful comparison. Although there was no challenge at trial to either the correctness or the veracity of this explanation, the ALJ nonetheless found that Modine intended to deceive the patent examiner. The ALJ also criticized Modine's description of the prior art and the arguments presented to the examiner concerning the prior art.

The Commission found that comparative data with Modine's most efficient prior condenser were included in graphs in the patent application, and that certain computer-generated early data were replaced with more accurate data. Substantial evidence supports the Commission's findings that there was neither material withholding nor intent to deceive in Modine's selection of data and in the prosecution of the patent application. We remark that the rule of *Kingsdown* evolved in response to the "plague" of collateral attacks, of which this is an example, wherein routine patent practice is challenged without substance. *See Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 939, 15 USPQ2d 1321, 1327 (Fed. Cir. 1990).

The holding that there was not inequitable conduct is affirmed.

Summary

Having interpreted the claims *de novo*, we vacate the Commission's rulings on the issues of infringement, and remand for findings and redetermination with respect to literal infringement and infringement under the doctrine of equivalents. In all other respects the Commission's decision is affirmed.

AFFIRMED IN PART, VACATED IN PART, AND REMANDED.

Mayer, J., dissents.

U.S. Court of Appeals
Federal Circuit

PPG Industries Inc. v. Guardian Industries Corp.

No. 95-1222

Decided February 6, 1996

PATENTS

1. Infringement — Literal infringement (§120.05)

Defendant's automotive glass infringes claims of patent for solar control glass, since accused glass satisfies all limitations of asserted independent and dependent claims, including level of ultraviolet transmittance no greater than 31 percent; inventors' miscalculation of ultraviolet transmittance level of claimed glass due to software error does not warrant contrary conclusion, even though ultraviolet transmittance of accused glass would appear to be above 31 percent if tested with inventors' inaccurate equipment, since asserted claims cover glass that transmits no more than 31 percent of sun's ultraviolet radiation, rather than glass that is measured at no more than 31 percent ultraviolet transmittance using flawed testing system.

2. Patentability/Validity — Specification — Claim adequacy (§115.1109)

Claims for solar control glass are not invalid for indefiniteness under 35 USC 112, even though inventors miscalculated ultraviolet transmittance level of claimed glass due to software error, since claims are precise in quantifying essential ingredients and transmittance tolerances of claimed compositions and give clear notice of what compositions fall within their range, since inventors thus distinctly claimed subject matter that they regarded as their invention despite misconception as to ultraviolet transmittance levels, and since inventors' failure to specify method to be used in testing ultraviolet transmittance does not render claims invalid.

3. Patentability/Validity — Specification — Enablement (§115.1105)

Specification of patent for solar control glass satisfies enablement requirement of 35 USC 112, even though inventors' miscalculation of ultraviolet transmittance level of claimed glass could lead careful reader of specification to conclude that glass with iron content and "redox" ratio of accused glass would not be likely to satisfy ultraviolet transmittance limitation of asserted claims, since embodiment of patent having same composition and transmittance properties as accused glass could be made by person of ordinary skill in art without "undue experimentation" in view of specification's provision of guidance in selecting operating parameters that would yield claimed result.

4. Patentability/Validity — Anticipation — Identity of elements (§115.0704)

Patentability/Validity — Obviousness — Relevant prior art — Particular inventions (§115.0903.03)

Infringement plaintiff is likely to prevail on issues of whether patent for "solar control glass" is anticipated or rendered obvious by prior Russian patent, since composition of prior patent contains significant amounts of rare earth elements that absorb ultraviolet radiation and visible light, and thus does not meet limitations of claimed glass, and since defendant has not rebutted showing that Russian patent teaches away from compositions of asserted claims, and has thus failed to show that one skilled in art would have been motivated to eliminate additional rare earth elements and would have had reasonable expectation of success in light of prior art.

REMEDIES

5. Non-monetary and injunctive — Equitable relief — Preliminary injunctions — Patents (§505.0707.07)

Patent infringement plaintiff's showing of likelihood of success on merits of infringement and validity issues warrants issuance of preliminary injunction, since plaintiff's showing on those issues is sufficiently strong to invoke presumption of irreparable harm, and since defendant has failed to rebut that presumption.

6. Non-monetary and injunctive — Equitable relief — Preliminary injunctions — Patents (§505.0707.07)

Federal district court did not abuse its discretion by finding that both balance of hardships and public interest favor issuance of injunction in action for infringement of patent for solar control glass, since court has not been unresponsive to defendant's interest in meeting its current contract obligations, or to public's interest in obtaining solar control glass.

Particular patents — Chemical — Solar control glass

5,240,886, Gulotta and Shelestak, ultraviolet absorbing, green tinted glass, grant of preliminary injunction in infringement suit affirmed.

Appeal from the U.S. District Court for the Western District of Pennsylvania, Lancaster, J.

Action by PPG Industries Inc. against Guardian Industries Corp. for patent infringement. From grant of plaintiff's motion for preliminary injunction, defendant appeals. Affirmed.

Arland T. Stein, Stanley D. Ference III, and Cynthia E. Kernick, of Reed Smith Shaw & McClay, and Mark Levin, of PPG Industries Inc., Pittsburgh, Pa., for plaintiff-appellee.

Daniel W. Vittum, Jr., and Jeffrey D. Mills, of Kirkland & Ellis, Chicago, Ill., for defendant-appellant.

Before Michel, Schall, and Bryson, circuit judges.

Bryson, J.

This case concerns a dispute between two major manufacturers of automotive glass; the dispute revolves around glass compositions known as "solar control glass," which have the highly desirable characteristics of filtering out most of the sun's ultraviolet and infrared radiation while transmitting most of the light in the visible part of the spectrum. Appellee PPG Industries, Inc., which holds a patent on a composition of solar control glass, sued appellant Guardian Industries Corporation for patent infringement and obtained a preliminary injunction from the United States District Court for the Western District of Pennsylvania. The injunction prohibits Guardian from making, using, or selling its own composition of solar control glass. We conclude that the district court did not abuse its discretion in granting preliminary injunctive relief to PPG, and we therefore affirm the order of the district court.

I

On August 31, 1993, the Patent and Trademark Office issued U.S. Patent No. 5,240,886 (the '886 patent), which was assigned to PPG. Shortly after obtaining the patent, PPG advised Guardian that it believed Guardian's solar control glass, known as "Solar Management Glass" (SMG), infringed PPG's rights under the patent. Litigation followed, and after a five-day hearing

the district court granted PPG's motion for a preliminary injunction.

The district court found that PPG had established a likelihood of success on the merits by making a strong showing that SMG infringed PPG's rights under the patent and that the patent was not invalid. In light of PPG's showing on the merits, the court held that PPG was entitled to a presumption that it would suffer irreparable harm from Guardian's continued infringement. The court also found that the balance of hardships and the public interest weighed in favor of granting PPG's request for preliminary injunctive relief. Guardian brought this appeal, contesting the district court's ruling on each of those points.

II

A

The issue to which the parties devote the most attention is whether Guardian infringed claim 1 of the '886 patent and dependent claims 3 and 4. Claim 1 of the '886 patent defines a glass composition consisting of soda-lime-silica glass to which is added a set of ingredients that have the effect of selectively filtering out most of the sun's ultraviolet radiation. The filtering ingredients are identified in the claim as cerium (in the form of cerium oxide (CeO2) and iron (in the ferric (Fe2O3) state). The claim requires that the composition have a total iron content of at least 0.85 percent by weight, and that the ratio of iron in the ferrous (FeO) state to total iron (known as the redox ratio) be no greater than 0.275. In full text, the claim reads as follows:

> 1. A green tinted, ultraviolet absorbing glass having a base glass composition consisting essentially of:
>
> | | |
> |---|---|
> | SiO_2 | 68-75 weight % |
> | Na_2 | 10-20 |
> | CaO | 5-15 |
> | MgO | 0-5 |
> | Al_2O_3 | 0-5 |
> | K_2O | 0-5 |
>
> and a colorant portion consisting essentially of:
>
> | | |
> |---|---|
> | CeO_2 | Less than 0.5 weight % |
> | Total Iron (as Fe_2O_3) | Greater than 0.85 weight % |
> | FeO/total iron | Less than 0.275. |
>
> exhibiting ultraviolet transmittance no greater than 31 percent (300 to 390 nanometers) and luminous transmittance (illuminant A) of at least 70 percent, both at a reference thickness of 3.9 millimeters.

Dependent claim 3 adds the limitation that the dominant wavelength of the light transmitted by the glass must be between 495 and 535 nanometers (the green color range of the spectrum), and dependent claim 4 adds the requirement that the glass must exhibit a total solar energy transmittance (including ultraviolet, visible, and infrared radiation) of less than 45 percent at a reference thickness of 3.9 millimeters.

The ultraviolet and visible light transmission requirements set forth in the claims are those established by the automotive industry as the minimum standards for acceptable solar control glass. Prior to the '886 invention (and Guardian's SMG glass), solar control glass was often made with a significant amount of cerium, a rare earth element, in the form of cerium oxide. The principal benefit of the invention claimed in the '886 patent, as explained in the specification, is that it permits a manufacturer of solar control glass to meet industry standards while adding either no cerium or relatively little cerium to the glass. Minimizing the amount of cerium used in the glass is valuable because cerium is expensive and because it has the undesirable effect, after long-term exposure to ultraviolet radiation, of darkening the glass in which it is present.

The specification of the '886 patent contains a set of examples of compositions falling within the scope of claim 1 of the patent. The examples include several compositions containing relatively small amounts of cerium (between 0.27 and 0.31 percent cerium by weight) and one composition containing essentially no cerium. Each of the examples satisfies the transmittance requirements of the claim for visible light and ultraviolet radiation. The example that contains no cerium, however, shows a particularly low redox ratio. A low redox ratio, together with a relatively large amount of iron, has the effect of compensating for the absence of cerium in filtering out ultraviolet radiation. With respect to the no-cerium example, the specification further states that

> the very low ferrous to total iron ratio required when no cerium is used may be difficult to attain in some melting furnaces. Therefore, it is preferred that a small amount of cerium be used to yield the desired reduction in ultraviolet transmittance without requiring an unduly low ferrous to total iron ratio.

While the '886 patent application was pending before the PTO, PPG obtained a sample of Guardian's SMG glass and tested it. When PPG's tests showed that the SMG sample did not meet the automobile manufacturers' standards for ultraviolet transmittance, PPG advised Guardian of those results. Guardian responded that under its tests SMG met the 31 percent ultraviolet transmittance requirement for the 300 to 390 nanometer range. When PPG re-examined its testing procedures, it discovered that the software it was using in its testing equipment was flawed and that as a result the testing equipment had made an error in calculating not only the ultraviolet transmittance of the SMG sample, but also the ultraviolet transmittance of each of the examples set forth in the '886 patent specification. Because of the software error, the ultraviolet transmittance reported in each example was about three percent too high; thus, the glass tested in each example was actually filtering out about three percent more ultraviolet radiation than the testing equipment indicated. That error had led the inventors to suggest in the specification that a glass meeting the limitations of the patent and containing no cerium at all might be difficult to make commercially, as it would require a redox ratio that would be hard to achieve in some commercial furnaces. In fact, however, the transmittance limitations of the claims for a no-cerium glass are not as difficult to satisfy as the specification suggests, because after an adjustment is made for the three percent calculation error, the redox ratio for the no-cerium embodiment does not have to be as low as the specification indicates.

Based on the three percent calculation error, Guardian argues that the claims of the '886 patent do not cover SMG. If the claims are read in light of the specification, Guardian argues, they cannot be construed to apply to SMG, because the examples in the specification make clear that the inventors did not believe that a glass having the composition of SMG would satisfy the 31 percent ultraviolet transmission requirement.

[1] The problem with Guardian's argument is that the claims simply cannot be construed as Guardian suggests. By their plain terms, the claims read on SMG: the critical limitations require that the glass contain less than 0.5 percent cerium and more than 0.85 percent iron, that the redox ratio of the iron components be less than 0.275, that the ultraviolet transmittance be no greater than 31 percent, and that the visible light transmittance be at least 70 percent. SMG satisfies all of those limitations and thus infringes claim 1 of the '886 patent. Moreover, because the dominant wavelength transmitted by SMG is within the green range (495 to 535 nanometers) and because SMG's total solar energy transmittance at the 3.9 millimeter reference thickness is less than 45 percent, it falls within the limitations of dependent claims 3 and 4 as well.

It is true that if Guardian's SMG glass is tested with the same flawed testing equipment that was used to prepare the examples in the '886 patent specification, SMG's ultraviolet transmittance would appear to be above the 31 percent maximum set forth in the claims. But the '886 patent claims are not qualified in that manner; the claims cover glass that transmits no more than 31 percent of the sun's ultraviolet radiation, not glass that is measured at no more than 31 percent ultraviolet transmittance with PPG's flawed testing system. Because it is undisputed that SMG transmits no more than 31 percent of the sun's ultraviolet radiation over the wavelength range of 300 to 390 nanometers, and because that is the way the ultraviolet transmittance limitation is specified in the patent claims, the claims cannot be construed in a way that renders SMG non-infringing.

B

In the alternative, Guardian argues that if the claims are interpreted to read on SMG, the patent is invalid under section 112 of the Patent Act, 35 U.S.C. § 112. Guardian makes three arguments in support of its section 112 claim. First, Guardian contends that the claims run afoul of the requirement of particularity and distinctness in paragraph 2 of section 112 because they fail to point out and distinctly claim what the inventors regarded as their invention. Second, Guardian argues that the claims violate paragraph 2 of section 112 for the additional reason that the inventors failed to state the method they used to measure the ultraviolet transmittance of the invention. Third, Guardian asserts that the patent is invalid because, in order for the claims to read on SMG, the claims must be interpreted as extending beyond the invention disclosed in the specification. In its reply brief, Guardian makes explicit that its third argument is based on the "enablement" requirement of paragraph 1 of section 112, not the "written description" requirement that appears in the same paragraph.

We reject each of the section 112 arguments on which Guardian relies. First, paragraph two of section 112 "is essentially a requirement for *precision and definiteness* of claim language," *In re Borkowski*, 422 F.2d 904, 909, 164 USPQ 642, 646 (CCPA 1970) (emphasis in original); the "requirement is that the language of the claims must make it clear what subject matter they encompass,"

In re Hammack, 427 F.2d 1378, 1382, 166 USPQ 204, 208 (CCPA 1970).

[2] There is nothing imprecise or indefinite about the claim language in the '886 patent. The claims are quite precise in quantifying the essential ingredients and transmittance tolerances of the claimed compositions: on their face, the claims give clear notice of what compositions fall within their scope. Because the claims "reasonably apprise those skilled in the art both of the utilization and scope of the invention," and because "the language is as precise as the subject matter permits," *Shatterproof Glass Corp.* v. *Libbey-Owens Ford Co.*, 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985) (internal quotation omitted), *cert. dismissed*, 474 U.S. 976 (1985), the claims are not invalid for indefiniteness.

Guardian argues that the patent nonetheless violates paragraph 2 of section 112 because the inventors would not have believed at the time of their application that glass having the composition of SMG could meet the transmittance limitations of the claims. That misconception on the part of the inventors, however, does not mean that they failed to "distinctly claim[ ] the subject matter which [they] regard[ed] as [their] invention." 35 U.S.C. § 112, ¶2. The inventors regarded their invention as a glass containing filtering ingredients within the defined composition ranges and producing an ultraviolet transmittance of no more than 31 percent and a visible light transmittance of at least 70 percent, and that is what they claimed. Guardian relies on cases in which the claims included "a substantial measure of inoperatives," *In re Corkill*, 771 F.2d 1496, 1501, 226 USPQ 1005, 1009 (Fed. Cir. 1985), or cases in which "some material submitted by applicant, *other than his specification*, shows that a claim does not correspond in scope with what *he regards* as his invention," *In re Conley*, 490 F.2d 972,976, 180 USPQ 454, 457 (CCPA 1974) (emphasis in original; citing *In re Cormany*, 476 F.2d 998, 177 USPQ 450 (CCPA 1973), and *In re Prater*, 415 F.2d 1393, 162 USPQ 541 (CCPA 1973)). In this case, by contrast, the claims were written in a manner that required all the embodiments to be operative; the claims set out exactly what the inventors intended to claim as their invention; and Guardian does not point to any statement by the applicants outside the specification that indicates that they did not intend to claim all species having the recited limitations. Moreover, nothing in the specification renders any of the claim language ambiguous, such that a person skilled in the art would be uncertain about "what subject matter falls within the scope of the claims." *In re Miller*, 441 F.2d 689, 692, 169 USPQ 597, 599 (CCPA 1971); *see In re Moore*, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). There is therefore no force to Guardian's argument that the claims did not accurately and distinctly set out what the inventors regarded as their invention.

Second, the patent is not rendered invalid on the ground that the inventors failed to specify the method to be used in measuring the ultraviolet transmittance set forth in the claims. The evidence at the preliminary injunction hearing established that, setting aside the equipment error that plagued PPG's testing procedures, all of the conventional methods of testing ultraviolet transmittance produce essentially identical results. Accordingly, the claim limitation of no more than 31 percent ultraviolet transmittance, in conjunction with the other limitations, is sufficiently definite to put the public on fair notice of what compositions fall within the scope of the claims. *See Hybritech, Inc.* v. *Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94-95 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987).

Third, the specification satisfies the enablement requirement of section 112, paragraph 1, which requires that the specification contain a description "of the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same." 35 U.S.C. § 112, ¶1. The specification of the '886 patent describes in ample detail how to make and use the invention with respect to the seven specific embodiments set forth in the experimental examples. And Guardian does not dispute that the specification enables all embodiments falling within the other claim limitations and having an ultraviolet transmittance of 28 percent or less (which is the transmittance that PPG's flawed testing equipment reported as 31 percent). The only contested issue is whether the '886 patent must be held invalid on the ground that the specification fails to satisfy the enablement requirement with respect to embodiments having an actual ultraviolet transmittance of less than 31 percent, but which PPG's equipment would have reported as more than 31 percent.

In pressing its enablement argument, Guardian focuses on the portion of the specification that suggests a particularly low redox ratio is necessary to satisfy the ultraviolet transmittance limitation if the patented invention is made without any cerium. The test results and the statement on which

Guardian relies are products of PPG's software error; the effect of the error was to make the ultraviolet transmittance figures appear artificially high and thus to make it appear that in order to attain the 31 percent ultraviolet transmittance limitation in the claims, the composition would need more iron and a lower redox ratio, both of which have the effect of reducing ultraviolet transmittance.

[3] We are not persuaded that the calculation error and the statements in the specification regarding the need for a low redox ratio in a no-cerium embodiment of the invention give rise to a violation of the enablement requirement. It is true that, in order to be enabling, a specification "must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 495-96, 20 USPQ2d 1438, 1444-45 (Fed. Cir. 1991). Moreover, Guardian is correct that a careful reader of the specification could well conclude that a glass with the iron content and redox ratio of SMG would not be likely to satisfy the ultraviolet transmittance limitation of the claims. The district court found, however, that PPG's calculation error was "harmless, inconsequential, and easily detectable by anyone who was skilled in the art of processing solar controlled glass." We interpret that statement as a factual finding that PPG's error could be discovered without "undue experimentation" by a person having ordinary skill in the art, and thus that the enablement requirement of section 112 was satisfied. *See In re Vaeck*, 947 F.2d at 495, 20 USPQ2d at 1444 ("Enablement . . . is a question of law which we independently review, although based upon underlying factual findings which we review for clear error.").

In light of the district court's finding, we cannot agree with Guardian that the specification of the '886 patent does not "teach those skilled in the art how to make and use the full scope of the claimed invention." *In re Wright*, 999 F.2d at 1561, 27 USPQ2d at 1513. In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim. *See, e.g., In re Goodman*, 11 F.3d 1046, 1050-52, 29 USPQ2d 2010, 2013-15 (Fed. Cir. 1993). *Amgen, Inc.* v. *Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1212-14, 18 USPQ2d 1016, 1026-28 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991); *In re Vaeck*, 947 F.2d at 496, 20 USPQ2d at 1445. Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made, based on the disclosure in the specification, without undue experimentation. But the question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation "must not be unduly extensive." *Atlas Powder Co.* v. *E.I. DuPont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). The Patent and Trademark Office Board of Appeals summarized the point well when it stated:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.

Ex parte Jackson, 217 USPQ 804, 807 (1982).

In this case, the district court was justified in finding that undue experimentation would not be required to make an embodiment of the '886 patent having the same composition and transmittance properties as SMG. One of the examples in the specification describes a glass containing no cerium, but having a lower redox ratio and a higher iron content than SMG. The specification teaches that as the iron content of the glass is reduced and the redox ratio rises, the glass transmits more ultraviolet radiation. A person reading the specification could therefore start with the no-cerium example and make a glass similar to SMG by simply lowering the iron content and allowing the redox ratio to rise until the ultraviolet transmittance reached the 31 percent limitation.

Another example given in the specification has roughly the same composition as SMG except that it contains a small amount of cerium. Following the principles taught in the specification, an experimenter could produce an embodiment of the '886 patent with a composition and properties similar to SMG simply by keeping the iron content and the redox ratio fixed, and reducing the cerium content to zero. In preparing that embodiment, the experimenter would discover that the ultraviolet transmittance calculations for the examples found in the patent specification are a few percent too high, but that error would not affect the experimenter's ability to make the desired embodiment.

Where the specification provides "guidance in selecting the operating parameters that would yield the claimed result," *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977) (Miller, J., concurring) (emphasis omitted), it is fair to conclude that the experimentation required to make a particular embodiment is not "undue." Although PPG's software error made it appear that commercial production of a no-cerium composition that satisfied the transmittance limitations would be difficult, the specification made it clear that such a composition could be made, and it indicated to one skilled in the art how to maintain low ultraviolet transmittance while minimizing the cerium content of the glass. Thus, the specification gave "considerable direction and guidance on how to practice [the] invention." *In re Wands*, 858 F.2d 731, 740, 8 USPQ2d 1400, 1406 (Fed. Cir. 1988).

In light of the guidance provided by the specification, this case is quite different from those in which enablement has been found lacking because of the need for "undue experimentation." *See, e.g., White Consol. Indus., Inc.* v. *Vega Servo-Control, Inc.*, 713 F.2d 788, 790-92, 218 USPQ 961, 962-64 (Fed. Cir. 1983) (a requirement of 18 months to two years' work to practice the patented invention is "undue experimentation"); *In re Ghiron*, 442 F.2d 985, 992, 169 USPQ 723, 727-28 (CCPA 1971) (a development period of " 'many months or years . . . does not bespeak a routine operation but of extensive experimentation and development work' "). It was therefore reasonable for the district court to conclude that the patent was not invalid for lack of enablement.

C

Guardian next contends that it does not infringe PPG's rights under the '886 patent, because SMG contains a sulfur compound that significantly affects its filtering properties, and the claims of the '886 patent therefore do not read on SMG glass. The district court acknowledged that SMG contains sulfur, but it found that the sulfur contained in SMG has no material effect on the filtering properties of the glass.

Guardian contends that the district court committed clear error in the factual finding it made on the sulfur issue. The court's finding, however, was based on an extensive exploration of the issue through testimony and documents at the five-day preliminary injunction hearing. Although Guardian introduced documentary evidence that sulfur can affect the transmittance properties of glass, Guardian did not persuade the district court — and has not persuaded us — that those authorities prove that sulfur has such an effect when the redox ratio is as low as it is in Guardian's accused SMG product.

Guardian challenges the testimony of PPG's expert on the sulfur issue, but the court heard testimony by experts from both sides and found PPG's expert testimony more convincing. Because we do not find PPG's presentation on the sulfur issue inherently implausible, we are satisfied that the district court's finding on that issue is not clearly erroneous.

D

Guardian's next argument is that PPG failed to satisfy its burden of showing that the '886 patent is likely to survive challenges based on Guardian's defenses of anticipation and obviousness. Before the district court, Guardian argued that example 4 in Russian Patent No. 948,912 anticipated, or at least rendered obvious, claim 1 of the '886 patent. Guardian urges that in rejecting its contention, the district court applied an erroneous legal standard and did not make sufficiently detailed factual findings to permit meaningful review by this court.

The district court concluded that there was no factual basis to support a finding of invalidity, because the Russian patent teaches that significant amounts of cerium and other rare earth elements that absorb ultraviolet light are necessary to reduce ultraviolet transmission to the level set forth in claim 1 of the '886 patent. To be sure, the district court did not articulate the correct legal standard when it stated that to invalidate a patent the prior reference must "give the same knowledge and the same directions" as the challenged patent. The ultimate question, however, is whether the challenger's evidence of invalidity is sufficiently persuasive that it is likely to overcome the presumption of patent validity. *See New England Braiding Co.* v. *A.W. Chesterton Co.*, 970 F.2d 878, 883, 23 USPQ2d 1622, 1625 (Fed. Cir. 1992). In view of the limited record presented to the district court on this issue, we agree with the court's conclusion that Guardian's argument based on the Russian patent failed to "raise[ ] a substantial question" of invalidity. *Id.*

[4] To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter. *Chester* v. *Miller*, 906 F.2d 1574, 1576 n.2, 15 USPQ2d 1333, 1336 n.2 (Fed. Cir. 1990); *In re Donohue*, 766 F.2d 531, 533, 226 USPQ 619, 621 (Fed. Cir. 1985). Guardian has not shown that the composition described in example 4 of the Russian patent meets the limitations of the claim, because that composition contains significant amounts of several rare earth elements that absorb ultraviolet radiation as well as visible light.

In presenting its defense of obviousness, Guardian again relied principally on the Russian patent. In the district court, however, Guardian did not demonstrate that the claimed invention would have been obvious to one skilled in the art in light of the disclosures in that reference. In its presentation to us, moreover, Guardian has not pointed to any evidence showing that the district court's factual finding that the Russian patent teaches away is clearly erroneous. Therefore, Guardian has failed to provide any basis for concluding that one skilled in the art would have been motivated to eliminate the additional rare earth elements recited in example 4 of the Russian patent and would have had a reasonable expectation of success in light of the prior art. *See In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). For purposes of the preliminary injunction proceedings, PPG has thus satisfied its burden of showing a likelihood of success on the validity issue.

E

Guardian also challenges the district court's conclusion that PPG would suffer irreparable harm if preliminary injunctive relief were not granted. Because the district court found that PPG had made a clear showing that it was likely to prevail on the issues of patent validity and infringement, the court held that PPG was entitled to a presumption of irreparable harm. *See H.H. Robertson Co.* v. *United Steel Deck, Inc.*, 820 F.2d 384, 390, 2 USPQ2d 1926, 1930 (Fed. Cir. 1987); *Atlas Powder Co.* v. *Ireco Chemicals*, 773 F.2d 1230, 1233, 227 USPQ 289, 292 (Fed. Cir. 1985). In addition, the district court found that in the absence of injunctive relief PPG's significant position in the solar control glass market would be threatened.

[5] Guardian places heavy reliance on this court's decision in *High Tech Medical Instrumentation, Inc.* v. *New Image Indus., Inc.*, 49 F.3d 1551, 33 USPQ2d 2005 (Fed. Cir. 1995), where the court reversed a preliminary injunction in part because of an inadequate showing of irreparable harm. In that case, however, the court concluded that the patentee was unlikely to succeed on the merits of its infringement claim and therefore held that the presumption of irreparable harm was inapplicable. 49 F.3d at 1556, 33 USPQ2d at 2009. In this case, by contrast, we have upheld the district court's conclusion that PPG is likely to succeed at the merits stage on the issues of infringement and validity, and we agree that PPG's showing on those issues was sufficiently strong to invoke the presumption of irreparable harm. Because we agree with the district court that Guardian failed to rebut that presumption, we sustain the court's ruling that PPG met its burden of showing that it would suffer irreparable harm in the absence of an order granting preliminary injunctive relief.

F

Finally, Guardian argues that the balance of hardships and the public interest both counsel in favor of denying the injunction. The district court, however, considered both factors and reached the contrary conclusion, and we are not prepared to overturn that determination. The district court concluded that PPG would suffer significant harm from the denial of an injunction, while an injunction would be less burdensome for Guardian, as it would require only a temporary interruption in Guardian's production and sale of its SMG glass. With regard to the public interest, the court acknowledged that an injunction would deprive the public of one of the suppliers of solar control glass. The court, however, balanced that interest against the strong public policy favoring the enforcement of patent rights. Because the court found it unlikely that the injunction would result in a shortage of solar control glass, the court found that, on balance, the public interest favored PPG.

[6] Guardian argues that PPG will be unable to satisfy the requirements of Guardian's customers, particularly the large automobile manufacturers, for solar control glass. To address that objection, however, the district court gave Guardian the right to return to court for relief from the preliminary injunction if Guardian were unable to fulfill its current contracts with automobile manufacturers, either with noninfringing compositions or by purchase from PPG on reasonable terms. Guardian made an initial request for temporary relief from the injunction, which was granted. The record does not reflect that Guardian has made any further requests, although the district court has made clear that it would be prepared to entertain any such requests if they should be

made. In the absence of a showing that the district court has been unresponsive to Guardian's interest in fulfilling its current contract obligations, or to the public's interest in obtaining an adequate supply of solar control glass, we cannot conclude that the district court abused its discretion in finding that both the balance of hardships and the public interest favor PPG.

III

The unusual circumstances surrounding the prosecution of the '886 patent have made this preliminary injunction proceeding difficult. Nonetheless, we have carefully reviewed each of the numerous legal points that Guardian has raised in challenging the injunction, and we conclude that none of them requires that we upset the district court's order. Guardian will have an opportunity at the merits stage to present and expand upon the arguments it has made at the preliminary injunction stage, as well as any additional arguments that it chooses to present, and the district court will be able to give those arguments plenary consideration at that time. The record as it now stands, however, compels us to conclude that the district court did not abuse its discretion in granting the preliminary injunction.

AFFIRMED.

U.S. Court of Appeals
Federal Circuit

Pro-Mold and Tool Co. v. Great Lakes Plastics Inc.

Nos. 95-1171, -1181

Decided February 7, 1996

PATENTS

1. Patentability/Validity — Obviousness — Relevant prior art — Particular inventions (§115.0903.03)

Patentability/Validity — Obviousness — Combining references (§115.0905)

Two holders for sports trading cards, viewed together, provide all elements in asserted claim of allegedly infringed patent for card holder, since one card holder includes all elements of invention except for size, and since second card holder, which is only slightly larger than stored trading card, provides size element; second card holder is prior art to patent in suit, since it was advertised in 1988, 1989, and 1990.

2. Patentability/Validity — Obviousness — Combining references (§115.0905)

Reason, suggestion, or motivation to combine two or more prior art references in single invention may come from references themselves, from knowledge of those skilled in art that certain references or disclosures in references are known to be of interest in particular field, or from nature of problem to be solved; in present case, motivation to combine friction-fit cover of one prior art sports trading card holder with small size of second card holder arose from size of trading cards themselves, since card holder that is substantially same size as trading card, and that would therefore be of proper size to fit within conventional storage set box, was clearly desirable.

3. Patentability/Validity — Obviousness — Commercial success (§115.0908)

Federal district court erred by granting summary judgment that plaintiff's patent for sports trading card holder is obvious, since plaintiff presented evidence that it sold approximately 3.2 million card holders in one year, since plaintiff's lack of previous experience in relevant market, combined with high sales of patented product, provides inference of nexus between commercial success and features of patented invention, since plaintiff's evidence of commercial success created genuine issues of material fact on question of obviousness, and since district court did not provide reasons for apparently discounting plaintiff's evidence of secondary considerations.

JUDICIAL PRACTICE AND PROCEDURE

4. Procedure — Court of Appeals for the Federal Circuit (§410.03)

Court of Appeals for the Federal Circuit will not defer to regional circuit law on issue of whether alleged inequitable conduct in prosecution of patent application constitutes unfair competition, since issue clearly impacts Federal Circuit's exclusive jurisdiction.

TRADEMARKS AND UNFAIR TRADE PRACTICES

5. Unfair competition — Other federal statutes (§395.06)

Patent infringement defendant's assertion that plaintiff acted in bad faith by filing infringement complaint knowing that patent was unenforceable does not establish claim for unfair competition under federal law, since there is no legal basis for holding that assertion of patent procured through inequitable conduct constitutes unfair competition, since defendant has not cited specific statutory provision that it claims plaintiff has violated, and since obtaining patent through inequitable conduct does not violate federal unfair competition statute, Lanham Act's Section 43(a), 15 USC 1125(a).

PATENTS

6. Patentability/Validity — Inventorship (§115.13)

Infringement — Defenses — Fraud or unclean hands (§120.1111)

Inventor of patent for sports trading card holder did not engage in inequitable conduct by failing to identify his son as joint inventor, since son, although "involved" in invention development process, admits that his father conceived idea of making card holder substantially same size as trading card so that it would fit in conventional set storage box, and since even if son's contribution was sufficient to make him joint inventor, there is no evidence that failure to identify son as such was due to intent to deceive Patent and Trademark Office concerning any matter material to patentability.

7. Patentability/Validity — Obviousness — Relevant prior art — Particular inventions (§115.0903.03)

Infringement — Defenses — Fraud or unclean hands (§120.1111)

Inventor of patent for sports trading card holder did not engage in inequitable conduct by failing to disclose prior art "Top Loader" card holder to Patent and Trademark Office, since "Top Loader" is one-piece flexible plastic sleeve rather than rigid plastic case claimed in patent, and does not fit into conventional card set storage box, since "Top Loader" thus lacked both size and structural features of prior art card holders available to examiner, and since it was therefore less relevant than prior art of which examiner was aware.

Particular patents — General and mechanical — Card holder

5,224,600, Neugebauer, card holder, summary judgment of invalidity vacated.

Appeal from the U.S. District court for the Northern District of Ohio, Katz, J.

Action by Pro-Mold and Tool Co. against Great Lakes Plastics Inc. for patent infringement, in which defendant counterclaims for unfair competition. From summary judgment of patent invalidity and dismissal of counterclaim, parties cross-appeal. summary judgment of invalidity vacated and remanded; judgment dismissing counterclaim affirmed.

Thomas F. Zych, of Thompson, Hine & Flory, Cleveland, Ohio; Mark D. Levy and Brian J. O'Connell, of Thompson, Hine & Flory, of Dayton, Ohio, for plaintiff-appellant.

Marshall A. Bennett, Jr. and D. Edward Dolgorukov, of Marshall & Mulhorn, Toledo, Ohio, for defendant/cross-appellant.

Before Plager, Lourie, and Rader, circuit judges.

Lourie, J.

Pro-Mold and Tool Company, Inc. appeals from the summary judgment of the United States District Court for the Northern District of Ohio holding U.S. Patent 5,224,600 invalid under 35 U.S.C. § 103 and dismissing its patent infringement claim. Great Lakes Plastics, Inc. cross-appeals from the district court's judgment dismissing its counterclaim for unfair competition. *Pro-Mold and Tool Co. v. Great Lakes Plastics, Inc.*, No. 3:93 CV 7412 (N.D. Ohio Sept. 12, 1994). Because the district court erred in holding that there were no genuine issues of material fact regarding nonobviousness of the subject matter of the patent, we vacate the district court's judgment holding the patent invalid and remand. Because the district court did not err in determining that there was a lack of evidence to support Great Lakes' counterclaim for unfair competition, we affirm the district court's judgment dismissing that counterclaim.

BACKGROUND

The patent in suit describes a card holder for storing baseball and other sports trading cards. The card holder consists of a base and cover. Figures 1 and 2 illustrate top and side sectional views, respectively, of the base, and Figure 3 illustrates a side view of the cover:

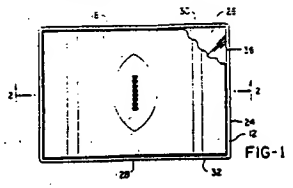

FIG-1

of Law will be entered on the same date herewith.

ORDER AND JUDGMENT

In accordance with the Findings of Fact and Conclusions of Law entered on the same date herewith,

IT IS HEREBY ORDERED AND ADJUDGED, as follows:

1. The Nolan patent (No. 4,506,189), issued on March 19, 1985, is a valid patent.
2. By the manufacture, production, sale and distribution of its SAF-T-COTE fluorescent lamp, Trojan has infringed the Nolan patent.
3. By virtue of this infringement, Shat-R-Shield is entitled to injunctive relief. Trojan shall immediately cease and desist from the manufacture, production, sale and distribution of the SAF-T-COTE fluorescent lamp.
4. Trojan shall recall all the SAF-T-COTE fluorescent lamps sold to and still in the possession of its customers.
5. The Court having determined that Trojan's infringement was not willful and wanton, Shat-R-Shield is not entitled to treble damages.
6. Shat-R-Shield shall have no accounting for monetary damages.
7. The Court having found that this is not an exceptional case, Shat-R-Shield is not entitled to its attorney's fees.
8. All claims having been resolved as to all parties herein, this action is now DISMISSED and STRICKEN from the docket.
9. There being no just reason for delay, this is a FINAL and APPEALABLE Order and Judgment.

Court of Appeals, Federal Circuit

In re Wands

No. 87-1454

Decided September 30, 1988

PATENTS

1. Patentability/Validity — Adequacy of disclosure (§115.12)

Data disclosed in application for immunoassay method patent, which shows that applicants screened nine of 143 cell lines developed for production of antibody necessary to practice invention, stored remainder of said cell lines, and found that four out of nine cell lines screened produced antibody falling within limitation of claims, were erroneously interpreted by Board of Patent Appeals and Interferences as failing to meet disclosure requirements of 35 USC 112, since board's characterization of stored cell lines as "failures" demonstrating unreliability of applicants' methods was improper in view of fact that such unscreened cell lines prove nothing concerning probability of success of person skilled in art attempting to obtain requisite antibodies using applicants' methods.

2. Patentability/Validity — Adequacy of disclosure (§115.12)

Disclosure in application for immunoassay method patent does not fail to meet enablement requirement of 35 USC 112 by requiring "undue experimentation," even though production of monoclonal antibodies necessary to practice invention first requires production and screening of numerous antibody producing cells or "hybridomas," since practitioners of art are prepared to screen negative hybridomas in order to find those that produce desired antibodies, since in monoclonal antibody art one "experiment" is not simply screening of one hybridoma but rather is entire attempt to make desired antibody, and since record indicates that amount of effort needed to obtain desired antibodies is not excessive, in view of applicants' success in each attempt to produce antibody that satisfied all claim limitations.

Appeal from decision of Patent and Trademark Office, Board of Patent Appeals and Interferences.

Application for patent of Jack R. Wands, Vincent R. Zurawski, Jr., and Hubert J. P. Schoemaker, serial number 188,735. From decision of Board of Patent Appeals and Interferences affirming rejection of application, applicants appeal. Reversed; Newman, J., concurring in part and dissenting in part in separate opinion.

Jorge A. Goldstein, of Saidman, Sterne, Kessler & Goldstein (Henry N. Wixon, with them on brief), Washington, D.C., for appellant.

John H. Raubitschek, associate solicitor (Joseph F. Nakamura and Fred E. McKelvey, with him on brief), PTO, for appellee.

Before Smith, Newman, and Bissell, circuit judges.

Smith, J.

This appeal is from the decision of the Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (board) affirming the rejection of all remaining claims in appellant's application for a patent, serial No. 188,735, entitled "Immunoassay Utilizing Monoclonal High Affinity IgM Antibodies," which was filed September 19, 1980.[1] The rejection under 35 U.S.C. §112, first paragraph, is based on the grounds that appellant's written specification would not enable a person skilled in the art to make the monoclonal antibodies that are needed to practice the claimed invention without undue experimentation. We reverse.

I. *Issue*

The only issue on appeal is whether the board erred, as a matter of law, by sustaining the examiner's rejection for lack of enablement under 35 U.S.C. §112, first paragraph, of all remaining claims in appellants' patent application, serial No. 188,735.

II. *Background*

A. *The Art.*

The claimed invention involves immunoassay methods for the detection of hepatitis B surface antigen by using high-affinity monoclonal antibodies of the IgM isotype. *Antibodies* are a class of proteins (immunoglobulins) that help defend the body against invaders such as viruses and bacteria. An antibody has the potential to bind tightly to another molecule, which molecule is called an antigen. The body has the ability to make millions of different antibodies that bind to different antigens. However, it is only after exposure of an antigen that a complicated *immune response* leads to the production of antibodies against that antigen. For example, on the surface of hepatitis B virus particles there is a large protein called *hepatitis B surface antigen* (HBsAg). As its name implies, it is capable of serving as an antigen. During a hepatitis B infection (or when purified HBsAg is injected experimentally), the body begins to make antibodies that bind tightly and specifically to HBsAg. Such antibodies can be used as reagents for sensitive diagnostic tests (*e.g.*, to detect hepatitis B virus in blood and other tissues, a purpose of the claimed invention). A method for detecting or measuring antigens by using antibodies as reagents is called an *immunoassay*.

Normally, many different antibodies are produced against each antigen. One reason for this diversity is that different antibodies are produced that bind to different regions (determinants) of a large antigen molecule such as HBsAg. In addition, different antibodies may be produced that bind to the same determinant. These usually differ in the tightness with which they bind to the determinant. *Affinity* is a quantitative measure of the strength of antibody-antigen binding. Usually an antibody with a higher affinity for an antigen will be more useful for immunological diagnostic tests than one with a lower affinity. Another source of heterogeneity is that there are several immunoglobulin classes or *isotypes*. Immunoglobulin G (IgG) is the most common isotype in serum. Another isotype, immunoglobulin M (IgM), is prominent early in the immune response. IgM molecules are larger than IgG molecules, and have 10 antigen-binding sites instead of the 2 that are present in IgG. Most immunoassay methods use IgG, but the claimed invention uses only IgM antibodies.

For commercial applications there are many disadvantages to using antibodies from serum. Serum contains a complex mixture of antibodies against the antigen of interest within a much larger pool of antibodies directed at other antigens. There are available only in a limited supply that ends when the donor dies. The goal of monoclonal antibody technology is to produce an unlimited supply of a single purified antibody.

The blood cells that make antibodies are *lymphocytes*. Each lymphocyte makes only one kind of antibody. During an immune response, lymphocytes exposed to their particular antigen divide and mature. Each produces a *clone* of identical daughter cells, all of which secrete the same antibody. Clones of lymphocytes, all derived from a single lymphocyte, could provide a source of a single homogeneous antibody. However, lymphocytes do not survive for long outside of the body in cell culture.

Hybridoma technology provides a way to obtain large numbers of cells that all produce the same antibody. This method takes advantage of the properties of *myeloma* cells derived from a tumor of the immune system. The cancerous myeloma cells can divide indefinitely in vitro. They also have the potential ability to secrete antibodies. By appropriate experimental manipulations, a myeloma cell can be made to fuse with a lymphocyte to produce a single hybrid cell (hence, a hybridoma) that contains the genetic material of both cells. The hybridoma secretes the same antibody that was made by its parent lymphocyte, but acquires the capability of the myeloma cell to divide and grow indefinitely in cell culture. Antibodies produced by a clone of hybridoma cells (i.e., by hybridoma

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[1] *In re Wands*, Appeal No. 673-76 (Bd. Pat. App. & Int. Dec. 30, 1986).

cells that are all progeny of a single cell) are called monoclonal antibodies.[2]

B. *The Claimed Invention.*

The claimed invention involves methods for the immunoassay of HBsAg by using high-affinity monoclonal IgM antibodies. Jack R. Wands and Vincent R. Zurawski, Jr., two of the three coinventors of the present application, disclosed methods for producing monoclonal antibodies against HBsAg in United States patent No. 4,271,145 (the '145 patent), entitled "Process for Producing Antibodies to Hepatitis Virus and Cell Lines Therefor," which patent issued on June 2, 1981. The '145 patent is incorporated by reference into the application on appeal. The specification of the '145 patent teaches a procedure for immunizing mice against HBsAg, and the use of lymphocytes from these mice to produce hybridomas that secrete monoclonal antibodies specific for HBsAg. The '145 patent discloses that this procedure yields both IgG and IgM antibodies with high-affinity binding to HBsAg. For the stated purpose of complying with the best mode requirement of 35 U.S.C. §112, first paragraph, a hybridoma cell line that secretes IgM antibodies against HBsAg (the 1F8 cell line) was deposited at the American Type Culture Collection, a recognized cell depository, and became available to the public when the '145 patent issued.

The application on appeal claims methods for immunoassay of HBsAg using monoclonal antibodies such as those described in the '145 patent. Most immunoassay methods have used monoclonal antibodies of the IgG isotype. IgM antibodies were disfavored in the prior art because of their sensitivity to reducing agents and their tendency to self-aggregate and precipitate. Appellants found that their monoclonal IgM antibodies could be used for immunoassay of HbsAg with unexpectedly high sensitivity and specificity. Claims 1, 3, 7, 8, 14, and 15 are drawn to methods for the immunoassay of HBsAg using high-affinity IgM monoclonal antibodies. Claims 19 and 25-27 are for chemically modified (*e.g.*, radioactively labeled) monoclonal IgM antibodies used in the assays. The broadest method claim reads:

> 1. An immunoassay method utilizing an antibody to assay for a substance comprising hepatitis B-surface antigen (HBsAg) determinants which comprises the steps of:
>
> contacting a test sample containing said substance comprising HBsAg determinants with said antibody; and
>
> determining the presence of said substance in said sample;
>
> wherein said antibody is a monoclonal high affinity IgM antibody having a binding affinity constant for said HBsAg determinants of at least 10^9 M^{-1}.

Certain claims were rejected under 35 U.S.C. §103; these rejections have not been appealed. Remaining claims 1, 3, 7, 8, 14, 15, 19, and 25-27 were rejected under 35 U.S.C. §112, first paragraph, on the grounds that the disclosure would not enable a person skilled in the art to make and use the invention without undue experimentation. The rejection is directed solely to whether the specification enables one skilled in the art to make the monoclonal antibodies that are needed to practice the invention. The position of the PTO is that data presented by Wands show that the production of high-affinity IgM anti-HBsAg antibodies is unpredictable and unreliable, so that it would require undue experimentation for one skilled in the art to make the antibodies.

III. *Analysis*

A. *Enablement by Deposit of Micro-organisms and Cell Lines.*

The first paragraph of 35 U.S.C. §112 requires that the specification of a patent must enable a person skilled in the art to make and use the claimed invention. "Patents * * * are written to enable those skilled in the art to practice the invention."[3] A patent need not disclose what is well known in the art.[4] Although we review underlying facts found by the board under a "clearly erroneous" standard,[5] we review enablement as a question of law.[6]

Where an invention depends on the use of living materials such as microorganisms or cultured cells, it may be impossible to enable the public to make the invention (i.e., to obtain these living materials) solely by means of a written disclosure. One means that has been developed for complying with the enablement requirement is to deposit the living materials in cell depositories which will distribute samples to the public who wish to practice the invention after the patent issues.[7] Administrative guidelines and judicial decisions have clarified the conditions under which a deposit of organisms can satisfy the requirements of section 112.[8] A deposit has been held necessary for enablement where the starting materials (i.e., the living cells used to practice the invention, or cells from which the required cells can be produced) are not readily available to the public.[9] Even when starting materials are available, a deposit has been necessary where it would require undue experimentation to make the cells of the invention from the starting materials.[10]

In addition to satisfying the enablement requirement, deposit of organisms also can be used to establish the filing date of the application as the prima facie date of invention,[11] and to satisfy the requirement under 35 U.S.C. §114 that the PTO be guaranteed access to the invention during pendency of the application.[12] Although a deposit may serve these purposes, we recognized, in *In re Lundak*,[13] that these purposes, nevertheless, may be met in ways other than by making a deposit.

A deposit also may satisfy the best mode requirement of section 112, first paragraph, and it is for this reason that the 1F8 hybridoma was deposited in connection with the '145 patent and the current application. Wands does not challenge the statements by the examiner to the effect that, although the deposited 1F8 line enables the public to perform immunoassays with antibodies produced by that single hybridoma, the deposit does not enable the generic claims that are on appeal. The examiner rejected the claims on the grounds that the written disclosure was not enabling and that the deposit was inadequate. Since we hold that the written disclosure fully enables the claimed invention, we need not reach the question of the adequacy of deposits.

B. *Undue Experimentation.*

Although inventions involving microorganisms or other living cells often can be enabled by a deposit,[14] a deposit is not always necessary to satisfy the enablement requirement.[15] No deposit is necessary if the biological organisms can be obtained from readily available sources or derived from readily available starting materials through routine screening that does not require undue experimentation.[16] Whether the specification in an application involving living cells (here, hybridomas) is enabled without a deposit must be decided on the facts of the particular case.[17]

Appellants contend that their written specification fully enables the practice of

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[2] For a concise description of monoclonal antibodies and their use in immunoassay see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1368-71, 231 USPQ 81, 82-83 (Fed. Cir. 1986), *cert. denied*, 107 S.Ct. 1606 (1987).

[3] *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1556, 220 USPQ 303, 315 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

[4] *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

[5] *Coleman v. Dines*, 754 F.2d 353, 356, 224 USPQ 857, 859 (Fed. Cir. 1985).

[6] *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1268, 229 USPQ 805, 810 (Fed. Cir. 1986), *cert. denied*, 107 S.Ct. 875 (1987); *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960 n.6, 220 USPQ 592, 599 n.6 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 [225 USPQ 232] (1984).

[7] *In re Argoudelis*, 434 F.2d 1390, 1392-93, 168 USPQ 99, 101-02 (CCPA 1970).

[8] *In re Lundak*, 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985); *Feldman v. Aunstrup*, 517 F.2d 1351, 186 USPQ 108 (CCPA 1975), *cert. denied*, 424 U.S. 912 [188 USPQ 720] (1976); Manual of Patent Examining Procedure (MPEP) 608.01 (p)(C) (5th ed. 1983, rev. 1987) *See generally* Hampar, *Patenting of Recombinant DNA Technology: The Deposit Requirement*, 67 J. Pat. Trademark Off. Soc'y 569 (1985)

[9] *In re Jackson*, 217 USPQ 804, 807-08 (Bd. App. 1982) (strains of a newly discovered species of bacteria isolated from nature); *Feldman*, 517 F.2d 1351, 186 USPQ 108 (uncommon fungus isolated from nature); *In re Argoudelis*, 434 F.2d at 1392, 168 USPQ at 102 (novel strain of antibiotic-producing microorganism isolated from nature); *In re Kropp*, 143 USPQ 148, 152 (Bd. App. 1959) (newly discovered microorganism isolated from soil).

[10] *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. & Int. 1986) (genetically engineered bacteria where the specification provided insufficient information about the amount of time and effort required); *In re Lundak*, 773 F.2d 1216, 227 USPQ 90 (unique cell line produced from another cell line by mutagenesis).

[11] *In re Lundak*, 773 F.2d at 1222, 227 USPQ at 95-96; *In re Feldman*, 517 F.2d at 1355, 186 USPQ at 113; *In re Argoudelis*, 434 F.2d at 1394-96, 168 USPQ at 103-04 (Baldwin, J. concurring).

[12] *In re Lundak*, 773 F.2d at 1222, 227 USPQ at 95-96; *In re Feldman*, 517 F.2d at 1354, 186 USPQ at 112.

[13] *In re Lundak*, 773 F.2d at 1222, 227 USPQ at 95-96.

[14] *In re Argoudelis*, 434 F.2d at 1393, 168 USPQ at 102.

[15] *Tabuchi v. Nubel*, 559 F.2d 1183, 194 USPQ 521 (CCPA 1977).

[16] *Id.* at 1186-87, 194 USPQ at 525; *Merck & Co. v. Chase Chem. Co.*, 273 F.Supp. 68, 77, 155 USPQ 139, 146 (D.N.J. 1967); *Guaranty Trust Co. v. Union Solvents Corp.*, 54 F.2d 400, 403-06, 12 USPQ 47, 50-53 (D. Del. 1931), *aff'd*, 61 F.2d 1041, 15 USPQ 237 (3d Cir. 1932), *cert. denied*, 288 U.S. 614 (1933); MPEP 608.01(p)(C) ("No problem exists when the microorganisms used are known and readily available to the public.").

[17] *In re Jackson*, 217 USPQ at 807; *see In re Metcalfe*, 410 F.2d 1378, 1382, 161 USPQ 789, 792 (CCPA 1969).

their claimed invention because the monoclonal antibodies needed to perform the immunoassays can be made from readily available starting materials using methods that are well known in the monoclonal antibody art. Wands states that application of these methods to make high-affinity IgM anti-HBsAg antibodies requires only routine screening, and that does not amount to undue experimentation. There is no challenge to their contention that the starting materials (i.e., mice, HBsAg antigen, and myeloma cells) are available to the public. The PTO concedes that the methods used to prepare hybridomas and to screen them for high-affinity IgM antibodies against HBsAg were either well known in the monoclonal antibody art or adequately disclosed in the '145 patent and in the current application. This is consistent with this court's recognition with respect to another patent application that methods for obtaining and screening monoclonal antibodies were well known in 1980.[18] The sole issue is whether, in this particular case, it would require undue experimentation to produce high-affinity IgM monoclonal antibodies.

Enablement is not precluded by the necessity for some experimentation such as routine screening.[19] However, experimentation needed to practice the invention must not be undue experimentation.[20] "the key word is 'undue,' not 'experimentation.' "[21]

> The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. Ansul Co. v. Uniroyal, Inc. [448 F.2d 872, 878-79; 169 USPQ 759, 762-63 (2d Cir. 1971), *cert. denied*, 404 U.S. 1018 [172 USPQ 257] (1972)]. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed * * *.[22]

The term "undue experimentation" does not appear in the statute, but it is well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation.[23] Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations. The board concluded that undue experimentation would be needed to practice the invention on the basis of experimental data presented by Wands. These data are not in dispute. However, Wands and the board disagree strongly on the conclusion that should be drawn from that data.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*.[24] They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.[25]

In order to understand whether the rejection was proper, it is necessary to discuss further the methods for making specific monoclonal antibodies. The first step for making monoclonal antibodies is to immunize an animal. The '145 patent provides a detailed description of procedures for immunizing a specific strain of mice against HBsAg. Next the spleen, an organ rich in lymphocytes, is removed and the lymphocytes are separated from the other spleen cells. The lymphocytes are mixed with myeloma cells, and the mixture is treated to cause a few of the cells to fuse with each other. Hybridoma cells that secrete the desired antibodies then must be isolated from the enormous number of other cells in the mixture. This is done through a series of screening procedures.

The first step is to separate the hybridoma cells from unfused lymphocytes and myeloma cells. The cells are cultured in a medium in which all the lymphocytes and myeloma cells die, and only the hybridoma cells survive. The next step is to isolate and clone hybridomas that make antibodies that bind to the antigen of interest. Single hybridoma cells are placed in separate chambers and are allowed to grow and divide. After there are enough cells in the clone to produce sufficient quantities of antibody to analyze, the antibody is assayed to determine whether it binds to the antigen. Generally, antibodies from many clones do not bind the antigen, and these clones are discarded. However, by screening enough clones (often hundreds at a time), hybridomas may be found that secrete antibodies against the antigen of interest.

Wands used a commercially available radioimmunoassay kit to screen clones for cells that produce antibodies directed against HBsAg. In this assay the amount of radioactivity bound gives some indication of the strength of the antibody-antigen binding, but does not yield a numerical affinity constant, which must be measured using the more laborious Scatchard analysis. In order to determine which anti-HBsAg antibodies satisfy all of the limitations of appellants' claims, the antibodies require further screening to select those which have an IgM isotype and have a binding affinity constant of at least 10^9 M^{-1}.[26] The PTO does not question that the screening techniques used by Wands were well known in the monoclonal antibody art.

During prosecution Wands submitted a declaration under 37 C.F.R §1.132 providing information about all of the hybridomas that appellants had produced before filing the patent application. The first four fusions were unsuccessful and produced no hybridomas. The next six fusion experiments all produced hybridomas that made antibodies specific for HBsAg. Antibodies that bound at least 10,000 cpm in the commercial radioimmunoassay were classified as "high binders." Using this criterion, 143 high-binding hybridomas were obtained. In the declaration, Wands stated that[27]

> It is generally accepted in the art that, among those antibodies which are binders with 50,000 cpm or higher, there is a very high likelihood that high affinity (Ka [greater than] 10^9 M^{-1}) antibodies will be found. However, high affinity antibodies can also be found among high binders of between 10,000 and 50,000, as is clearly demonstrated in the Table.

The PTO has not challenged this statement.

The declaration stated that a few of the high-binding monoclonal antibodies from two fusions were chosen for further screening. The remainder of the antibodies and the hybridomas that produced them were saved by freezing. Only nine antibodies were subjected to further analysis. Four (three from one fusion and one from another fusion) fell within the claims, that is, were IgM antibodies and had a binding affinity constant of at least 10^9 M^{-1}. Of the remaining five antibodies, three were found to be IgG, while the other two were IgM for which the affinity constants were not measured (although both showed binding well above 50,000 cpm).

Apparently none of the frozen cell lines received any further analysis. The declaration explains that after useful high-affinity IgM monoclonal antibodies to HBsAg had been found, it was considered unnecessary to return to the stored antibodies to screen for more IgMs. Wands says that the existence of the stored hybridomas was disclosed to the PTO to comply with the requirement under 37 C.F.R. §1.56 that applicants fully disclose all of their relevant data, and not just favorable results.[28] How these stored hybridomas are viewed is central to the positions of the parties.

The position of the board emphasizes the fact that since the stored cell lines were not completely tested, there is no proof that any of them are IgM antibodies with a binding affinity constant of at least 10^9 M^{-1}. Thus, only 4 out of 143 hybridomas, or 2.8 percent, were *proved* to fall within the claims. Furthermore, antibodies that were proved to be high-affinity IgM came from only 2 of 10 fusion experiments. These statistics are viewed by the board as evidence that appellants' methods were not predictable or reproducible. The board concludes that Wands' low rate of demonstrated success shows that a person skilled in the art would have to

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[18] *Hybritech*, 802 F.2d at 1384, 231 USPQ at 94.

[19] *Id.*; *Atlas Powder Co. v. E.I. DuPont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984); *In re Angstadt*, 537 F.2d at 502-504, 190 USPQ at 218; *In re Geerdes*, 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974); *Mineral Separation, Ltd. v. Hyde*, 242 U.S. 261, 270-71 (1916).

[20] *Hybritech*, 802 F.2d at 1384, 231 USPQ at 94; *W.L. Gore*, 721 F.2d at 1557, 220 USPQ at 316; *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977) (Miller, J., concurring).

[21] *In re Angstadt*, 537 F.2d at 504, 190 USPQ at 219.

[22] *In re Jackson*, 217 USPQ at 807.

[23] *See Hybritech*, 802 F.2d at 1384, 231 USPQ at 94; *Atlas Powder*, 750 F.2d at 1576, 224 USPQ at 413.

[24] *Ex parte Forman*, 230 USPQ at 547.

[25] *Id.*; *see In re Colianni*, 561 F.2d at 224, 195 USPQ at 153 (Miller, J., concurring); *In re Rainer*, 347 F.2d 574, 577, 146 USPQ 218, 221 (CCPA 1965).

[26] The examiner, the board, and Wands all point out that, technically, the strength of antibody-HBsAg binding is measured as *avidity*, which takes into account multiple determinants on the HBsAg molecule, rather than affinity. Nevertheless, despite this correction, all parties then continued to use the term "affinity." We will use the terminology of the parties. Following the usage of the parties, we will also use the term "high-affinity" as essentially synonymous with "having a binding affinity constant of at least 10^9 M^{-1}."

[27] A table in the declaration presented the binding data for antibodies from every cell line. Values ranged from 13,867 to 125,204 cpm, and a substantial proportion of the antibodies showed binding greater than 50,000 cpm. In confirmation of Dr. Wand's statement, two antibodies with binding less than 25,000 cpm were found to have affinity constants greater than 10^9 M^{-1}.

[28] *See Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 220 USQ 98 (Fed. Cir. 1983).

engage in undue experimentation in order to make antibodies that fall within the claims.

Wands views the data quite differently. Only nine hybridomas were actually analyzed beyond the initial screening for HBsAg binding. Of these, four produced antibodies that fell within the claims, a respectable 44 percent rate of success. (Furthermore, since the two additional IgM antibodies for which the affinity constants were never measured showed binding in excess of 50,000 cpm, it is likely that these also fall within the claims.) Wands argues that the remaining 134 unanalyzed, stored cell lines should not be written off as failures. Instead, if anything, they represent partial success. Each of the stored hybridomas had been shown to produce a high-binding antibody specific for HBsAg. Many of these antibodies showed binding above 50,000 cpm and are thus highly likely to have a binding affinity constant of at least 10^9 M^{-1}. Extrapolating from the nine hybridomas that were screened for isotype (and from what is well known in the monoclonal antibody art about isotype frequency), it is reasonable to assume that the stored cells include some that produce IgM. Thus, if the 134 incompletely analyzed cell lines are considered at all, they provide some support (albeit without rigorous proof) to the view that hybridomas falling within the claims are not so rare that undue experimentation would be needed to make them.

The first four fusion attempts were failures, while high-binding antibodies were produced in the next six fusions. Appellants contend that the initial failures occurred because they had not yet learned to fuse cells successfully. Once they became skilled in the art, they invariably obtained numerous hybridomas that made high-binding antibodies against HBsAg and, in each fusion where they determined isotype and binding affinity they obtained hybridomas that fell within the claims.

Wands also submitted a second declaration under 37 C.F.R. §1.132 stating that after the patent application was submitted they performed an eleventh fusion experiment and obtained another hybridoma that made a high-affinity IgM anti-HBsAg antibody. No information was provided about the number of clones screened in that experiment. The board determined that, because there was no indication as to the number of hybridomas screened, this declaration had very little value. While we agree that it would have been preferable if Wands had included this information, the declaration does show that when appellants repeated their procedures they again obtained a hybridoma that produced an antibody that fit all of the limitations of their claims.

[1] We conclude that the board's interpretation of the data is erroneous. It is strained and unduly harsh to classify the stored cell lines (each of which was proved to make high-binding antibodies against HBsAg) as failures demonstrating that Wands' methods are unpredictable or unreliable.[29] At worst, they prove nothing at all about the probability of success, and merely show that appellants were prudent in not discarding cells that might someday prove useful. At best, they show that high-binding antibodies, the starting materials for IgM screening and Scatchard analysis, can be produced in large numbers. The PTO's position leads to the absurd conclusion that the more hybridomas an applicant makes and saves without testing the less predictable the applicant's results become. Furthermore, Wands' explanation that the first four attempts at cell fusion failed only because they had not yet learned to perform fusions properly is reasonable in view of the fact that the next six fusions were all successful. The record indicates that cell fusion is a technique that is well known to those of ordinary skill in the monoclonal antibody art, and there has been no claim that the fusion step should be more difficult or unreliable where the antigen is HBsAg than it would be for other antigens.

[2] When Wands' data is interpreted in a reasonable manner, analysis considering the factors enumerated in *Ex parte Forman* leads to the conclusion that undue experimentation would not be required to practice the invention. Wands' disclosure provides considerable direction and guidance on how to practice their invention and presents working examples. There was a high level of skill in the art at the time when the application was filed, and all of the methods needed to practice the invention were well known.

The nature of monoclonal antibody technology is that it involves screening hybridomas to determine which ones secrete antibody with desired characteristics. Practitioners of this art are prepared to screen negative hybridomas in order to find one that makes the desired antibody. No evidence was presented by either party on how many hybridomas would be viewed by those in the art as requiring undue experimentation to screen. However, it seems unlikely that undue experimentation would be defined in terms of the number of hybridomas that were never screened. Furthermore, in the monoclonal antibody art it appears that an "experiment" is not simply the screening of a single hybridoma, but is rather the entire attempt to make a monoclonal antibody against a particular antigen. This process entails immunizing animals, fusing lymphocytes from the immunized animals with myeloma cells to make hybridomas, cloning the hybridomas, and screening the antibodies produced by the hybridomas for the desired characteristics. Wands carried out this entire procedure three times, and was successful each time in making at least one antibody that satisfied all of the claim limitations. Reasonably interpreted, Wands' record indicates that, in the production of high-affinity IgM antibodies against HBsAG, the amount of effort needed to obtain such antibodies is not excessive. Wands' evidence thus effectively rebuts the examiner's challenge to the enablement of their disclosure.[30]

[29] Even if we were to accept the PTO's 2.8% success rate, we would not be required to reach a conclusion of undue experimentation. Such a determination must be made in view of the circumstances of each case and cannot be made solely by reference to a particular numerical cutoff.

[30] *In re Strahilevitz*, 668 F.2d 1229, 1232, 212 USPQ 561, 563 (CCPA 1982).

IV. *Conclusion*

Considering all of the factors, we conclude that it would not require undue experimentation to obtain antibodies needed to practice the claimed invention. Accordingly, the rejection of Wands' claims for lack of enablement under 35 U.S.C. §112, first paragraph, is reversed.

REVERSED

Newman, J., concurring in part, dissenting in part.

A

I concur in the court's holding that additional samples of hybridoma cell lines that produce these high-affinity IgM monoclonal antibodies need not be deposited. This invention, as described by Wands, is not a selection of a few rare cells from many possible cells. To the contrary, Wands states that all monoclonally produced IgM antibodies to hepatitis B surface antigen have the desired high avidity and other favorable properties, and that all are readily preparable by now-standard techniques.

Wands states that his United States Patent No. 4,271,145 describes fully operable techniques, and is distinguished from his first four failed experiments that are referred to in the Rule 132 affidavit. Wands argues that these biotechnological mechanisms are relatively well understood and that the preparations can be routinely duplicated by those of skill in this art, as in *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 107 S.Ct. 1606 (1987). I agree that it is not necessary that there be a deposit of multiple exemplars of a cell system that is readily reproduced by known, specifically identified techniques.

B

I would affirm the board's holding that Wands has not complied with 35 U.S.C. §112, first paragraph, in that he has not provided data sufficient to support the breadth of his generic claims. Wands' claims on appeal include the following:

> 19. Monoclonal high affinity IgM antibodies immunoreactive with HBsAg determinants, wherein said antibodies are coupled to an insoluble solid phase, and wherein the binding affinity constant of said antibodies for said HBsAg determinants is at least 10^9 M^{-1}.
>
> 26. Monoclonal high affinity IgM antibodies immunoreactive with hepatitis B surface antigen.

Wands states that he obtained 143 "high binding monoclonal antibodies of the right specificity" in the successful fusions; although he does not state how they were determined to be high binding or of the right specificity, for Wands also states that only nine of these 143 were tested.

Of these nine, four (three from one fusion and one from another fusion) were found to have the claimed high affinity and to be of the IgM isotype. Wands states that the other five were either of a different isotype or their affinities were not determined. (This latter statement also appears to contradict his statement that all 143 were "high binding".)

Wands argues that a "success rate of four out of nine", or 44.4%, is sufficient to support claims to the entire class. The Commissioner deems the success rate to be four out of 143, or 2.8%; to which Wands responds with statistical analysis as to how unlikely it is that Wands selected the only four out of 143 that worked. Wands did not, however, prove the right point. The question is whether Wands, by testing nine out of 143 (the Commissioner points out that the randomness of the sample was not established), and finding that four out of the nine had the desired properties, has provided sufficient experimental support for the breadth of the requested claims, in the context that "experi-

ments in genetic engineering produce, at best, unpredictable results", quoting from *Ex parte Forman*, 230 USPQ 546, 547 (Bd.Pat.App. and Int. 1986).

The premise of the patent system is that an inventor, having taught the world something it didn't know, is encouraged to make the product available for public and commercial benefit, by governmental grant of the right to exclude others from practice of that which the inventor has disclosed. The boundary defining the excludable subject matter must be carefully set: it must protect the inventor, so that commercial development is encouraged; but the claims must be commensurate with the inventor's contribution. Thus the specification and claims must meet the requirements of 35 U.S.C. §112. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 23-24 (CCPA 1970).

As the science of biotechnology matures the need for special accommodation, such as the deposit of cell lines or microorganisms, may diminish; but there remains the body of law and practice on the need for sufficient disclosure, including experimental data when appropriate, that reasonably support the scope of the requested claims. That law relates to the sufficiency of the description of the claimed invention, and if not satisfied by deposit, must independently meet the requirements of Section 112.

Wands is not claiming a particular, specified IgM antibody. He is claiming all such monoclonal antibodies in assay for hepatitis B surface antigen, based on his teaching that such antibodies have uniformly reproducible high avidity, free of the known disadvantages of IgM antibodies such as tendency to precipitate or aggregate. It is incumbent upon Wands to provide reasonable support for the proposed breadth of his claims. I agree with the Commissioner that four exemplars shown to have the desired properties, out of the 143, do not provide adequate support.

Wands argues that the law should not be "harsher" where routine experiments take a long time. However, what Wands is requesting is that the law be less harsh. As illustrated in extensive precedent on the question of how much experimentation is "undue", each case must be determined on its own facts. *See, e.g., W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557, 220 USPQ 303, 316 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 218 (CCPA 1976); *In re Cook*, 439 F.2d 730, 734-35, 169 USPQ 298, 302-03 (CCPA 1971).

The various criteria to be considered in determining whether undue experimentation is required are discussed in, for example, *Fields v. Conover*, 443 F.2d 1386, 170 USPQ 276 (CCPA 1971); *In re Rainer*, 347 F.2d 574, 146 USPQ 218 (CCPA 1965); *Ex parte Forman*, 230 USPQ at 547. Wands must provide sufficient data or authority to show that his results are reasonably predictable within the scope of the claimed generic invention, based on experiment and/or scientific theory. In my view he has not met this burden.

Patent and Trademark Office
Trademark Trial and Appeal Board

In re Johanna Farms Inc.

Serial No. 542,343

Decided June 30, 1988

JUDICIAL PRACTICE AND PROCEDURE

1. Procedure — Prior adjudication — In general (§410.1501)

Trademark Trial and Appeal Board's prior decision upholding examiner's refusal to register proposed mark "La Yogurt" does not preclude registration of mark pursuant to subsequent application, since applicant, by presenting survey evidence and consumer letters regarding issue of how purchasers perceive proposed mark, has demonstrated that instant factual situation is different from situation presented in prior proceeding.

TRADEMARKS AND UNFAIR TRADE PRACTICES

2. Types of marks — Non-descriptive — Particular marks (§327.0505)

Term "La Yogurt," with "yogurt" disclaimed, is registrable, since word "yogurt" is common English generic term rather than corruption or misspelling of French word for yogurt, since examining attorney failed to meet burden of showing clear evidence of generic use of mark as whole, and since evidence of record, including survey and consumer letters to applicant, demonstrates that primary significance of "La Yogurt" to majority of relevant public is that of brand name rather than generic term.

3. Registration and its effects — Federal registration — Procedure, form and content — Disclaimer (§315.0303.10)

Types of marks — Non-descriptive — Particular marks (§327.0505)

French article "La" combined with English generic term in proposed mark "La Yogurt" changes commercial impression of mark as whole and renders it registrable, since applicant's competitors would have no need to use "La Yogurt" mark as whole, other than to trade on applicant's good will, in view of applicant's disclaimer of word "yogurt."

Appeal from refusal of registration (Mark Traphagen, trademark examining attorney, Paul Fahrenkopf, managing attorney).

Related decisions: 222 USPQ 607, 223 USPQ 459.

Application of Johanna Farms Inc. for registration of trademark, serial no. 542,343, filed June 11, 1985. From decision refusing registration, applicant appeals. Reversed; Simms, Member, dissenting in separate opinion.

Lerner, David, Littenberg, Krumholz & Mentlik, Westfield, N. J., for applicant.

Before Sams, Rich, Rooney, Simms, Krugman, Cissel, Seeherman, and Hanak, members.

Krugman, Member.

An application has been filed by Johanna Farms, Inc. to register the term "LA YOGURT" ("YOGURT" disclaimed) as a trademark on the Principal Register for yogurt.[1] Applicant seeks registration pursuant to Section 2(f) of the Trademark Act based on the claim that the designation sought to be registered has acquired distinctiveness.

Registration has been refused on two grounds. First, the Examining Attorney maintains that registration herein is barred under the doctrine of stare decisis in view of a final decision rendered by the Board in connection with a prior application to register "LA YOGURT" for yogurt.[2] The Examining Attorney maintains that the relevant circumstances involved in the present case are identical to those considered in the prior application and that applicant is precluded from relitigating issues which have already been determined.

As a second ground for refusal, the Examining Attorney asserts that, even if it is determined that stare decisis does not bar registration herein, the phrase "LA YOGURT" is a generic designation, incapable of distinguishing applicant's goods from those of others; that "YOGURT" is the French generic name for the goods; that use of the French article "LA" in combination with "YOGURT" yields only an ungrammatical variation on the foreign generic term for the goods and that evidence of de facto secondary meaning cannot elevate the generic term sought to be registered to the status of a registrable trademark.

Applicant has appealed.

In view of the issues presented by this case, the oral hearing on November 17, 1987 was held before the eight members of the Trademark Trial and Appeal Board sitting, by designation of the Chairman of the Trademark Trial and Appeal Board, as an augmented panel.

Turning first to the issue of stare decisis, a brief review of the circumstances of the prior application and the Board's decision relating thereto are in order.

Applicant initially filed an application to register "LA YOGURT" as a trademark for yogurt on the Principal Register.[3] After registration was refused on the ground that the term sought to be registered was "merely the name of the goods," applicant amended its application to one seeking registration on the Supplemental Register. Eventually, registration was finally refused on the Supplemental Register on the ground that "LA YOGURT" was nothing more than the apt (generic) name of the goods and that said term, therefore, was unregistrable on the Supplemental Register. Applicant then appealed.

The Board, in deciding the appeal, noted that "yogurt" was concededly the name of the goods and that the term "la" had no significance by itself in relation to yogurt or any other product, other than as the French feminine article modifying the generic term. The Board then stated that the question to be decided was whether the entire term "LA YOGURT" was generic. If it were, the Board stated, the term could not be registered on either the Principal or Supplemental Register. If, however, "LA YOGURT" were not generic, it would be registrable on the Principal Register. In either case, the

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[1] Application Serial No. 542,343 filed June 11, 1985.

[2] In re Johanna Farms, Inc., 222 USPQ 607 (TTAB 1984), reconsideration denied, 223 USPQ 459 (TTAB 1984).

[3] Application Ser. No. 171,952 filed May 2, 1978.

there were mutual accounts, the accounts were too complicated for a jury to resolve or when there was a fiduciary relationship between the parties. *Medtronic*, 725 F.2d at 443; 4 Pomeroy §1421 at 1077–81; See J. Eichengrun, *Remedying the Remedy of Accounting*, 60 Ind.L.J. 463 (1984–85) (Eichengrun). None of these possible bases for equitable jurisdiction over Hartmarx's claim for profits are present in this case.

It has been stated that "restitution for the disgorgement of unjust enrichment is an equitable remedy with no right to a trial by jury. *Roberts v. Sears, Roebuck & Co.*, 617 F.2d 460, 465 [207 USPQ 788] (7th Cir. 1980),[4] and there can be an action for restitution where no injunction is sought in which there is no right to jury trial. See 5 Moore's Federal Procedure ¶38.24[2] at 38–206 (2d ed. 1988). But "the origins of unjust enrichment are both legal and equitable," *Medtronic*, 729 F.2d at 443, and it is not clear that "an accounting is equitable merely because the underlying theory of the case is unjust enrichment." *Id.* "The common law action of account is noteworthy as the earliest example of a restitutionary action, imposing on the defendant the obligation to disclose and return profits from the use of the plaintiff's property to prevent unjust enrichment." Eichengrum at 465. See also *Camrex (Holdings) Ltd. v. Camrex Reliance Paint Co, Inc.*, 90 F.R.D. 313, 322–23 (E.D.N.Y. 1981); 4 Pomeroy at §1047 at 101–102.

Further, while an infringer's profits may be seen as "unjust enrichment", we question whether an action for their recovery is necessarily "restitution" in the trademark context. "Profits are awarded under different rationales including unjust enrichment, deterrence, and compensation." *Roulo v. Russ Berrie & Co., Inc.*, 886 F.2d 931, 941 [12 USPQ 23] (7th Cir. 1989), *cert. denied*, 110 S.Ct. 1124, 107 L.Ed.2d 1030 (1990). A court of equity may require the infringer to pay over his profits because he should not be allowed to profit from his own wrong or because the actual loss to the trademark owner is impossible to compute, but this is arguably more in the nature of compensatory damages than restoring the trademark owner's own property to him, which is what is normally understood by restitution.

As a practical matter, an award of profits is really a surrogate for damages. Unless he can show diversion of sales, a trademark owner will be hard pressed to prove damages, and even if he shows confusion of the marks and diversion of customers it is difficult to show how many customers bought the infringer's product who would have bought the trademark owner's but for the deception. (Few purchasers of cheap "knockoffs" of expensive goods would have bought the genuine article.) The damage caused by the dilution of the owner's goodwill when the infringer's goods are of inferior quality is virtually impossible to quantify. At least in some circumstances the infringer's profits may be a rough measure of the owner's damages, and an award of profits affords some compensation to the trademark owner. See *Louis Vuitton S.A. v. Lee*, 875 F.2d 584, 589 [10 USPQ2d 1939] (7th Cir. 1989) (plaintiff "is entitled at the very least either to simple damages or to the [innocent infringer's] profits.").

We conclude that a claim for a trademark infringer's profits is more analogous to a suit for damages than one for restitution. Congress recognized the difficulty of computing appropriate compensation for trademark infringement, and directed the court to combine damages *and* profits to achieve a just result. That profits were combined with damages in Section 1117 into a single monetary recovery which constitutes "compensation", rather than included in Section 1116, the section authorizing injunctions, suggests that Congress considered an award of profits more in the nature of damages than as incidental to equitable relief.

While Congress gave the court discretion to adjust the amount to be awarded, this discretion does not render the proceeding equitable. In *Tull*, 481 U.S. at 425–26, the Supreme Court held that a suit for an injunction and civil penalty under the Clean Water Act was a "legal" action carrying with it the right to a jury trial, even though the amount of the penalty was to be determined by the court rather that the jury.

[2] Because trademark actions were historically legal, because an equitable accounting for profits was not granted except when there was some other basis of equitable jurisdiction, because an award of profits in the trademark context is more like an award of damages than restitution and because any doubts should be resolved in favor of the policy expressed in *Beacon Theatres* and *Dairy Queen* favoring jury trials of factual issues, we believe that *Dairy Queen, Ross* and *Curtis* entitled Hartmarx to a jury trial on its claim for profits under 15 U.S.C. §1117.

[3] Since the jury trial was proper in this case the court may overturn its findings of fact only under the standards for granting a motion for judgment notwithstanding the verdict. The court does not agree with the Oxford's contention, based on the Fifth Circuit's opinion in *Sheila's Shine Products, Inc. v. Sheila Shine, Inc.*, 486 F.2d 114 at 121–22 [179 USPQ 577] (5th Cir. 1973), that the court may make its own findings of fact in deciding whether to grant an injunction. While the court sitting in equity has considerable discretion in determining the scope of an injunction, it may not substitute its own findings on validity or infringement unless it properly enters a judgment notwithstanding the verdict on the legal claim. See *Hussein v. Oshkosh Motor Truck Co.*, 816 F.2d 348, 355 (7th Cir. 1987) (jury's verdict on §1981 claim would bind the court in considering equitable relief under Title VII). Otherwise the jury's verdict would not be *res judicata* as to the issues properly submitted for jury determination. *In re Lewis*, 845 F.2d 624, 629 (6th Cir. 1988).

Oxford's motion to vacate the judgment entered December 1, 1989 is granted. Oxford's motion for the entry of the court's findings of fact and conclusions of law is denied.

Pending before the court are the following:

(1) Oxford motion for directed verdict, judgment notwithstanding the verdict and for new trial. Oxford shall submit its brief in support of this motion by May 15, 1990. Hartmarx's response will be due May 22, 1990, and Oxford's reply by May 29, 1990.

(2) Hartmarx motion for attorney's fees and costs. Oxford's response is due May 15, 1990 and Hartmarx's reply May 22, 1990.

(3) Hartmarx motion for injunction. This motion has been briefed. Oxford argues that an additional hearing is needed before the issue of injunctive relief may be determined. Oxford is to submit by May 15, 1990 an offer of proof setting forth the facts not contained in the record which it proposes to establish at such a hearing. That statement shall specify how each such fact will be proved, i.e., by documents or testimony, identifying the specific documents and witnesses. Hartmarx shall respond to that offer of proof by May 22, 1990, and shall include a statement specifying which facts listed in Oxford's offer of proof are disputed.

A hearing is set for June 14, 1990 at 2:30 p.m. at which time the court will hear argument on all pending motions and any additional matters which must be addressed before the entry of final judgment.

[4] In *First National Bank of Waukesha v. Warren*, 796 F.2d 999, 1000 (7th Cir. 1986), the Seventh Circuit characterized the statement in *Roberts* as "obiter dictum" and said, "terms such as 'restitution' and 'unjust' enrichment have slowly changed from distinctive forms of action to measures of damages available in actions of all sorts. [citations omitted] The evolution of the legal terms, coupled with the merger of the court systems, makes it difficult to say when a request for 'restitution' or 'constructive trust' is distinctively legal and when it is distinctively equitable — if these distinctions any longer have meaning for remedies measured solely in money."

Court of Appeals, Federal Circuit

In re Spada

No. 90-1109

Decided August 10, 1990

PATENTS

1. Patentability/Validity — Anticipation — Prior art (§115.0703)

Rejection for anticipation requires, as first step in inquiry, that all elements of claimed invention be described in single reference, and such reference must describe applicant's claimed invention sufficiently to have placed person of ordinary skill in possession of

2. Patentability/Validity — Anticipation — Prior art (§115.0703)

Discovery of new property or use of previously known composition, even if unobvious from prior art, cannot impart patentability to claims to known composition.

3. Patentability/Validity — Anticipation — Prior art (§115.0703)

Board of Patent Appeals and Interferences did not err in finding that virtual identity of monomers and procedures between claimed pressure-sensitive adhesive composition and prior art is sufficient to support prima facie case of unpatentability of polymer latex claims for lack of novelty applicant has burden, in face of such prima facie case, of showing that his polymer compositions are different from those described by prior art, and such burden is not met by simply including assertedly different properties in claims.

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Application for patent, serial no. 859,05 filed May 2, 1986 by Lonnie T. Spada and Joseph J. Wilczynski. From decision rejecting claims, applicants appeal. Affirmed.

James H. Laughlin, Jr., of Benoit, Smith Laughlin, Arlington Va. (Michael

Laird, Brea, Calif., with him on brief), for appellant.

John H. Raubitschek, associate solicitor (Fred E. McKelvey, solicitor, with him on brief), for appellee.

Before Newman and Mayer, circuit judges, and G.E. Brown, district judge (District of New Jersey, sitting by designation).

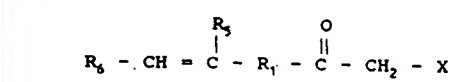
Newman, J.

The decision of the United States Patent and Trademark Office (the PTO) Board of Patent Appeals and Interferences (the Board), rejecting claims 2 through 25 and 27 through 31, all the claims at issue of Spada and Wilczynski (hereinafter Spada) patent application Serial No 859,057, filed May 2, 1986 and entitled "Pressure Sensitive Adhesives and Manufactured Articles", is affirmed.

The Invention

The Spada invention is a pressure sensitive adhesive composition comprising a water-based latex containing a normally tacky copolymer made from specified classes and proportions of monomers and having a glass transition temperature (T_g)[1] of 0°C or less. Claim 31 was treated by the parties as representative:

> Claim 31. A pressure sensitive adhesive composition comprising a water-base latex comprising a continuous aqueous medium containing dispersed particles of a normally tacky polymer having a T_g of about 0°C. or less and comprising at least about 60 weight percent olefinically unsaturated carboxylic acid ester monomers and at least about 0.1 weight percent of at least one polymerizable functional monomer of the formula:



in which R_1 is a divalent organic radical of at least 3 atoms in length, R_5 and R_6 are independently selected from hydrogen, hydroxy, halo, thio, amino or monovalent organic radicals, and X is -Co-R_4 or -CN wherein R_4 is hydrogen or a monovalent organic radical.

The Spada disclosure broadly is coextensive with claim 31. While claim 31 requires that the polymers comprise members of two general classes of monomers, Spada's specific examples illustrate polymers in which members of three general classes of monomers are present.

The first class of monomer required by Spada is an olefinically unsaturated carboxylic acid ester that is present in at least about 60 weight percent of the polymer. Representative examples show 96.5 weight percent butyl acrylate (Example 2), and a combination of 48 weight percent butyl acrylate and 48 weight percent 2-ethylhexyl acrylate (Example 11).

Spada's second required class of monomer is a "polymerizable functional monomer" present in "at least about 0.1 weight percent" of the polymer (claim 31). The illustrative examples show 1-2 weight percent acetoacetoxyethyl methacrylate (AAEMA).

Spada's specification states that preferred polymer compositions include at least about 0.1 weight percent of a third class of monomer, an olefinically unsaturated carboxylic acid. Examples are 1.5 weight percent methacrylic acid (Example 2) and 3 weight percent acrylic acid (Example 7).

All of Spada's claims require that the T_g of the claimed tacky polymers is about 0°C or less, and that the products are pressure-sensitive adhesives.

The claims were rejected as unpatentable in view of the Smith reference, United States Patent No. 3,554,987, issued January 12, 1971. The Spada disclosure and the Smith reference both show polymers of the same monomers, in overlapping ratios of components. However, the products that Smith and Spada obtain are described as quite different.

The Smith Reference

Smith describes water-based latexes containing dispersed particles of polymers made from certain classes and proportions of monomers. The polymers are used in binding agents in photographic gels and films.

In most of Smith's examples three monomers are present, as in Spada's examples. The first monomer in Smith's preferred polymers is an olefinically unsaturated carboxylic acid ester, in at least 50 percent by weight of polymer. In Smith's examples this component is illustrated, inter alia, as 75.7 molar percent butyl acrylate (Example 5), and 72.4 weight percent ethyl acrylate (Example 15).

[1] Glass transition temperature (T_g) is defined as the temperature (or temperature range) at which an amorphous polymer changes from a hard, rigid, glassy state to a soft, flexible, rubbery state. S. Rosen, *Fundamental Principles of Polymeric Materials* §8.1 (1982).

Smith's second monomer used in preparing his preferred polymers is a polymerizable functional monomer like that described by Spada, present in about 2–20 weight percent of the polymer. Smith's examples include polymers containing 9.4 molar percent of acetoacetoxyethyl acrylate (AAEA) (Example 5), and 3.5 weight percent AAEMA (Example 15). Spada incorporated by reference the entire disclosure of the Smith patent, as showing polymerizable functional monomers suitable and preferred for use in the Spada polymers, and the preparation of these monomers.

The preferred polymers of Smith contain a third monomer, as do Spada's, and most of Smith's examples include acrylic acid. Thus, in Smith's Example 5 the complete polymer composition is 75.7 molar percent butyl acrylate, 9.4 molar percent AAEA, and 14.9 molar percent acrylic acid. In Smith's Example 15 the composition is 72.4 weight percent ethyl acrylate, 3.5 weight percent AAEMA, and 24.1 weight percent acrylic acid.

Smith states that emulsions containing his polymers have improved properties of hardness, resistance to abrasion, good adhesion, and dimensional stability. Smith does not show or suggest that his polymer latexes can form a normally tacky pressure-sensitive adhesive — properties admitted to be different from hardness and abrasion resistance.

Discussion

The Board affirmed the rejection of Spada's claims under 35 U.S.C. §102/103, this hybrid rejection having apparently been made on the theory that if the claimed subject matter was novel, i.e. not anticipated, in terms of section 102, then it would have been obvious under section 103.[2] The Commissioner on this appeal concentrates on the rejection for anticipation. The Commissioner argues that a *prima facie* case[3] of anticipation is made by the Smith disclosure of polymers that are apparently identical to those of Spada, although the properties described by Smith are different from those that are reported by Spada and included as express limitations in Spada's claims.

[1] Rejection for anticipation or lack of novelty requires, as the first step in the inquiry, that all the elements of the claimed invention be described in a single reference. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir.), *cert. denied*, 110 S.Ct. 154 (1989). Further, the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it. *Akzo N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1479, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909 (1987); *In re Coker*, 463 F.2d 1344, 1348, 175 USPQ 26, 29 (CCPA 1972).

Spada argues that Smith does not describe Spada's claimed invention, for to find anticipation "all limitations in the claims must be found in the reference since the claims measure the invention." *In re Lange*, 644 F.2d 856, 862, 209 USPQ 288, 293 (CCPA 1981). Spada states that since his compositions are claimed as pressure-sensitive adhesives containing a tacky polymer having a T_g below 0°C, they can not be anticipated. Spada argues that since the Smith products are hard, abrasion-resistent solids, they are *ipso facto* different.

[2] The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition.[4] *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780, 782, 227 USPQ 773, 777–78, 778 (Fed. Cir. 1985); *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974); *In re Lemin*, 326 F.2d 437, 440, 140 USPQ 273, 276 (CCPA 1964). Thus, the initial inquiry is to the novelty of the composition. *Titanium Metals*, 778 F.2d at 780, 227 USPQ at 777.

The Board held that the compositions claimed by Spada "appear to be identical" to those described by Smith. While Spada criticizes the usage of the word "appear", we think that it was reasonable for the PTO to infer that the polymerization by both Smith and Spada of identical monomers, employing

[2] The court has accepted the PTO's practice of basing rejections on section 102 or 103 in the alternative, provided that the appellant was fully apprised of all the grounds of rejection. *See, e.g., In re Pearson*, 494 F.2d 1399, 1402 & nn. 2–3, 181 USPQ 641, 644 & nn. 2–3 (CCPA 1974).

[3] The *prima facie* case is a procedural tool which, as used in patent examination (as by courts in general), means not only that the evidence of the prior art would reasonably allow the conclusion the examiner seeks, but also that the prior art compels such a conclusion if the applicant produces no evidence or argument to rebut it. *See Black's Law Dictionary* 107 (5th Ed. 1979). *See generally In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984) (citing cases showing the evolution of the concept in patent examination of *prima facie* obviousness as a legal inference drawn from uncontradicted evidence). Upon rebuttal, the decision is made on the entirety of the record. *Id.*

[4] All of Spada's claims are composition claims. The issue is not before us of whether Spada may have discovered a new use of a known composition, which use may be patentable as a process. 35 U.S.C. §101. *See In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957).

the same or similar polymerization techniques, would produce polymers having the identical composition. Products of identical chemical composition can not have mutually exclusive properties. *See In re Papesch*, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963) (a chemical compound and its properties are inseparable).

[3] While the art and science of polymer chemistry may be distinguished from that of simpler compounds and compositions, in Spada's case we conclude that the Board correctly found that the virtual identity of monomers and procedures sufficed to support a *prima facie* case of unpatentability of Spada's polymer latexes for lack of novelty. See, e.g., *In re Thorpe*, 777 F.2d 695, 697-98, 227 USPQ 964, 966 (Fed. Cir. 1985), wherein the examiner's rejection of product-by-process claims under §102/103, based on similarity of reactants, reaction conditions, and properties, amounted to a *prima facie* case of unpatentability.

In response to the PTO's asserted *prima facie* case the applicant may argue that the inference of lack of novelty was not properly drawn, for example if the PTO did not correctly apply or understand the subject matter of the reference, or if the PTO drew unwarranted conclusions therefrom. However, when the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); *In re Ludtke*, 441 F.2d 660, 664, 169 USPQ 563, 566 (CCPA 1971). Spada offered no such showing.

The Board suggested that Spada provide some scientific explanation for the asserted differences between the properties of his compositions and those described by Smith. While an inventor is not required to understand how or why an invention works, we think that the PTO was correct, in view of the apparent identity of the compositions, in requiring Spada to distinguish [5] his compositions from those of Smith. Although newly discovered properties can be the basis of claims to *novel* polymers, *E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1435, 7 USPQ2d 1129, 1133 (Fed. Cir.), *cert. denied*, 109 S.Ct. 542 (1988), Spada did not overcome, with argument or evidence, the apparent chemical identity of his polymers and those of Smith. Spada showed no error, in science or in law, in the Board's holding that the products appeared to be the same and thus that Spada's products were not new.

Spada pointed to his data wherein polymers containing varying amounts of AAEMA showed greatly increased shear strength without significant loss in tack, compared with polymers without the AAEMA. We agree with Spada that this result is not suggested in the Smith reference. However, these data did not relate to the fundamental question of the novelty of Spada's compositions in view of those of Smith. Without novelty, evidence of unobviousness is superfluous.

As we observed *supra*, discovery of an unobvious property and use does not overcome the statutory restraint of section 102 when the claimed composition is known. While Spada's position is that his polymers are not anticipated by the polymers of Smith because their properties are different, Spada was reasonably required to show that his polymer compositions are different from those described by Smith. This burden was not met by simply including the assertedly different properties in the claims. When the claimed compositions are not novel they are not rendered patentable by recitation of properties, whether or not these properties are shown or suggested in the prior art.

The Board's decision rejecting all of the claims is

AFFIRMED.

[5] It was discussed at oral argument that the Spada invention may not be "particularly point-[ed] out and distinctly claim[ed]", in the words of 35 U.S.C. §112, paragraph 2. No rejection had been made under section 112. The Solicitor stated that such a rejection was inappropriate because the claims were "not vague". *But see Burlington Indus. v. Quigg*, 822 F.2d 1581, 1583-84, 3 USPQ2d 1436, 1438 (Fed. Cir. 1987) (whether claims were too broadly written is not a section 103 determination but an issue of claim imprecision under section 112). *See also In re Muchmore*, 433 F.2d 824, 824-25, 167 USPQ 681, 682 (CCPA 1970) ("there is sometimes a close relationship between indefiniteness under §112, second paragraph and obviousness under §103").

District Court, E.D. Michigan

Dana Corp. v. IPC Limited Partnership

No. 86-CV-70231-DT

Decided April 10, 1990 and May 21, 1990

PATENTS

1. Infringement — Defenses — Breach of duty of disclosure or inequitable conduct (§120.1111)

REMEDIES

Monetary — Attorney's fees; costs — Patents (§510.0905)

Patent infringement plaintiff's failure to disclose fluoride surface treatment necessary for satisfactory performance of patented seal constitutes material non-disclosure that warrants judgment of patent invalidity for failure to disclose best mode, but such conduct, although grossly negligent, cannot be said, when viewed in light of all evidence, including evidence of good faith, to demonstrate plaintiff's intent to deceive, and thus award of attorney's fees to defendant under 35 USC 285 is not warranted.

2. Monetary — Attorney's fees; costs — Patents (§510.0905)

Costs to obtain letters of credit to secure supersedeas bonds, which were incurred in order to lessen amount of bond premiums, are reasonable and are recoverable under Fed.R.Civ.P. 39(e).

Action filed by Dana Corp. against IPC Limited Partnership and International Packings Corp. for infringement of patent no. 3,498,621. On defendants' motion for reconsideration of order denying attorney's fees, and on defendants' motion for entry of final judgment order, including award of costs. Motion for reconsideration denied; motion for final judgment order, including costs, granted.

Prior decision: 8 USPQ2d 1692.

Ernie L. Brooks and Kevin Heinl, of Brooks & Kushman, Southfield, Mich., for plaintiff.

Michael R. Dinnin and Robert A. Dunn, of Dinnin & Dunn, Troy, Mich., for defendants.

Zatkoff, J.

This matter is currently before the Court on IPC's motion for reconsideration. IPC has moved this Court to reconsider its August 10, 1989 Memorandum Opinion and Order denying IPC's motion for attorney fees.

FACTUAL AND PROCEDURAL HISTORY

Dana Corporation sued IPC Limited Partnership and International Packings Corporation for patent infringement of U.S. Patent No. 3,498,621 (hereafter '621) owned by Dana. A jury found the '621 patent valid and enforceable. The jury also found willful infringement of the patent by defendants. The Court denied IPC's motion for judgment notwithstanding the verdict. IPC appealed the denial of JNOV. The Federal Circuit reversed and granted judgment for the defendants. The Federal Circuit found the '621 patent failed to disclose the best mode as required by 35 U.S.C. §112 and declared the patent invalid. Specifically, the Federal Circuit found that the '621 patent failed to disclose that a fluoride surface treatment is necessary for satisfactory performance of the patented seal.

Defendants filed for attorney fees pursuant to 35 U.S.C. §285. Under §285, the Court can award reasonable attorney fees to the prevailing party in exceptional circumstances. The Court found that imposition of attorney fees under 35 U.S.C. §285 would only be appropriate under a finding that concealment of the best mode was intentional.

In its April 28, 1989 Memorandum Opinion and Order, this Court found that according to the Wilson Report, the inventor of the '621 patent contemplated that the seal must be subject to a fluoride surface treatment. The Court also stated that the inventor had this belief at the time the patent application was filed, but Dana failed to disclose the necessity of fluoride treatment in the patent specification. Furthermore, the Court concluded that in an affidavit submitted to the Patent and Trademark Office, Dana omitted relevant data from the Wilson Report, which demonstrated that valve seals not subjected to fluoride treatment were unsatisfactory for their intended purpose. Dana also failed to provide this pertinent evidence to defendants or this Court until the close of evidence.

Dana's failure to disclose the necessity of fluoride treatment was material according to the Federal Circuit. As a result of this material omission, the Federal Circuit found that Dana had failed to satisfy the best mode requirement of 35 U.S.C. §112. Therefore, the patent was declared invalid. Upon the Federal Circuit's ruling that Dana's failure to disclose was a material omission, this Court reasoned that Dana was grossly negligent. This Court then cited to *J.P. Stevens & Co., Inc. v. Lex-Tex Ltd., Inc.*, 747 F.2d 1553, 1560 [223 USPQ 1089] (Fed. Cir. 1984) and ruled that intent could be shown by gross negligence. The Court, thereupon, found the case to be exceptional under 35 U.S.C. §285 and awarded reasonable attorney fees to defendants.

Plaintiff filed a motion for reconsideration on August 10, 1989. This Court granted plaintiff's motion, thereby vacating the Order of April 28, 1989. In its motion for reconsideration, plaintiff claimed the intent standard set forth in *J.P. Stevens* was no longer applicable in light of the Federal Circuit's recent *en banc* decision in *Kings-*

forced by counsel's answer to a question at the oral hearing when he stated that a hypothetical competitor's wrap ring consisting of identically placed gems but of *equal* size would not be considered an infringement of applicant's designs. However, it is very likely that others who examine applicant's confusing language may reach contrary conclusions concerning what applicant's mark might be. It is my firm belief that in these kinds of cases a much more direct and less confusing description should be required by the Examining Attorney. It is suggested, therefore, that in the unlikely event that applicant should ultimately prevail in any appeal, these applications be remanded to the Examining Attorney for the entry of a direct and clear description of applicant's claimed marks.

An additional issue raised by this case is applicant's attempt to limit the class of purchasers by the limitation in its description of goods. Where the product bearing a mark is ultimately purchased by members of the general public, any limitation in the identification (and in proof of secondary meaning) to vendors and retailers, is problematical. However, that issue need not be decided because of, among other things, the nature of applicant's marks and the lessened probative value to be given to declarations from persons who are presumably very familiar with these jewelry items and knowledgeable about their source.

U.S. Court of Appeals
Federal Circuit

Rowe v. Dror

No. 96-1304

Decided April 21, 1997

PATENTS

1. Patent construction — Claims — Broad or narrow (§125.1303)

Phrase "balloon angioplasty catheter," which appears only in preamble of application, is affirmative structural limitation of applicant's claim, which is not drawn to general purpose balloon catheter, since "Jepson" form of claim indicates applicant's intention to use preamble to define, in part, structural elements of claimed invention, and device for which applicant claims "an improvement" is "a balloon angioplasty catheter," since language in applicant's specification limits claimed "balloon angioplasty catheters" to catheters that can be inflated radially outward to dilate narrowed region in blood vessel, and since claim language requiring that microcapsules on surface of balloon contain drug for treatment "or diagnosis within a body lumen" is consistent with limiting claim to angioplasty apparatus.

2. Practice and Procedure in Patent and Trademark Office — Interference — In general (§110.1701)

Patent construction — Claims — In general (§125.1301)

Application claim must be interpreted in light of specification in which it appears, rather than with reference to patent from which it was copied, in interference in which issue is whether claim is patentable to party in light of prior art; rule that copied claim is interpreted in light of its originating disclosure applies in context of issue of whether applicant is eligible to copy patentee's claim and thereby challenge priority of invention.

3. Patentability/Validity — Anticipation — Identity of elements (§115.0704)

Patent for general purpose catheter having swab or balloon with microcapsules for applying medicine into body duct does not anticipate application claim for balloon angioplasty catheter having microcapsules on outer surface of balloon for administration of medicinal or diagnostic drugs during angioplasty procedure, since neither administrative patent judge nor Board of Patent Appeals and Interferences indicated that patent discloses "balloon angioplasty catheter," since applicant's opponent in interference did not argue, either before PTO or on appeal, that patent discloses "balloon angioplasty catheter," and since opponent's failure to deny applicant's clear allegations is tantamount to admission.

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Interference no. 103,157 between Stanton J. Rowe (application no. 07/865,781) and Michael Dror and Paul Trescony (patent no. 5,102,402). From final decision holding that prior art patent anticipates both parties' claims corresponding to interference count, applicant Stanton J. Rowe appeals. Reversed and remanded.

George H. Gerstman and Terrence W. McMillin, of Ellis & McMillin, Chicago, Ill., for appellant.

Bruce M. Collins, Ronald Gould, Glen E. Books, and Scott N. Bernstein, of Mathews, Woodbridge & Collins, Princeton, N.J., and Daniel W. Latham, of Medtronic, Inc., Minneapolis, Minn., for appellees.

Before Lourie, circuit judge, Friedman, senior circuit judge, and Rader, circuit judge.

Rader, J.

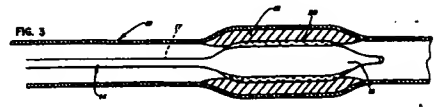
This is an appeal from a final decision in Interference No. 103,157. The interference involves United States Patent Application No. 07/865,781, filed by Stanton J. Rowe (Rowe) with a priority date of March 14, 1989 and assigned to Cordis Corp. (Rowe application), and United States Patent No. 5,102,402, issued to Michael Dror and Paul Trescony (collectively, Dror) based on an application filed on January 4, 1991 and assigned to Medtronic, Inc. (Dror patent). The Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (Board) found that Jerome H. Lemelson's United States Patent No. 4,900,303 (Lemelson patent) anticipated both parties' claims corresponding to the count. Because the Board clearly erred in finding anticipation, this court reverses and remands.

BACKGROUND

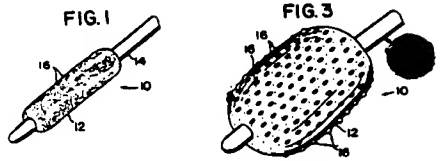
The subject matter of this interference relates generally to balloon angioplasty catheters. These catheters include a balloon that inflates within a blood vessel to reduce internal blockage and allow blood to flow freely. In particular, the balloon catheters aid angioplasty procedures by treating an area of stenosis, or accumulated plaque along the inner walls of a blood vessel. *See generally C.R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc.*, 911 F.2d 670, 671, 15 USPQ2d 1540, 1541 (Fed. Cir. 1990) (describing angioplasty procedures). In such a procedure, the balloon catheter inflates radially in the area of stenosis, thereby compressing the plaque against the blood vessel walls.

The balloon angioplasty catheters in this case have a covering of microcapsules on the outer surface of the balloon. These microcapsules can administer a medicinal or diagnostic substance during the angioplasty procedure. The action of the balloon inflating against the inner wall of a vessel ruptures the microcapsules and releases the substance. The microcapsules may administer, for example, a chemical that will cause the accumulated plaque to harden and maintain its dilated shape, or a chemical that will cause dissolution of the plaque.

Figure 3 of the Rowe application illustrates a balloon catheter used in an angioplasty operation. The illustration shows an angioplasty catheter (14) with a balloon section (16) in an area of stenosis (12) in a coronary artery (10). The balloon has expanded the stenosis and, simultaneously, deposited a therapeutic agent (20).



Similarly, Figures 1 and 3 of the Dror patent illustrate a balloon catheter (10) having an inflatable balloon (12) covered with microcapsules (16).



Although Rowe is the senior party in this interference, the Dror patent issued before completion of the examination of the Rowe application, which is still pending. When the Dror patent issued, Rowe copied several claims from the Dror patent into his application. The PTO declared an interference and designated the first copied claim as the sole interference count. That count, which corresponds to claims 53-66 of the Rowe application and claims 1-8, 10-15 and 17-21 of the Dror patent, reads:

> 1. In a balloon *angioplasty* catheter of the type comprising a catheter body and *a balloon positioned along the length of the catheter body*, said balloon including *means for remotely inflating and deflating said balloon*; the improvement comprising:
>
> (a) a plurality of microcapsules on the exterior of said balloon, each of said microcapsules carrying a drug or combination of drugs for treatment or diagnostics within a body lumen when said catheter is positioned and inflated therewithin such that the drug or drugs may be released from said microcapsules.

(Emphasis added to show disputed passages).

During the motion period before the PTO, Dror filed a motion seeking judgment

against Rowe on the ground that the Lemelson patent anticipated some of Rowe's claims corresponding to the count. *See* 37 C.F.R. § 1.633(a) (1996).

The Lemelson patent describes a general purpose catheter with a swab or balloon (with microcapsules) for applying medicine into a body duct. Figure 12 of the Lemelson patent shows the head of a catheter with a tubular catheter sidewall (137) surrounding a medicated swab (144). The medicated swab (144) may extend out the end of the catheter (by the pushing action of a piston (140)) to apply medicine to internal body tissue. The reference teaches as well that the swab (144) could carry the medicine in microcapsules.

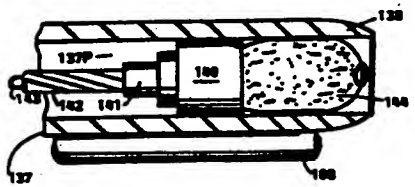


FIG. 12

Although the Lemelson patent does not illustrate a balloon catheter, it teaches that the medicated swab (144) in Figure 12 "may be replaced by an inflatable enclosure, such as a rubber finger or balloon, which is controllably inflated from within the catheter chamber or upon being projected therefrom as described."

Acting on Dror's motion, the administrative patent judge found that the Lemelson patent anticipates all of Rowe's and Dror's claims corresponding to the count.[1] The Board upheld the decision of the administrative patent judge and entered final judgment against both Rowe and Dror. Rowe filed this appeal. On appeal Rowe contends that the Board erred by failing to treat "angioplasty" as a claim limitation. Rowe further argues that the Lemelson patent cannot anticipate his claims because it discloses neither "a balloon positioned along the length of the catheter body" nor a "means for remotely inflating and deflating said balloon."

DISCUSSION

The PTO may, during the course of an interference, determine the patentability of any claim involved in the interference. *See* 37 C.F.R. § 1.633(a) (1996) (allows a party to an interference to move for judgment against the other party on the grounds that the count is not patentable to that party for any reason other than priority or derivation); *see also* 37 C.F.R. § 1.641 (1996) (allows administrative patent judge to raise the issue of patentability *sua sponte*). In such cases, the PTO is passing on the patentability of claims, not counts. *See In re Van Geuns*, 988 F.2d 1181, 1184, 26 USPQ2d 1057, 1059 (Fed. Cir. 1993). Thus, the PTO must separately determine the patentability of each claim in the interference, just as it would in an *ex parte* prosecution. *See Eiselstein v. Frank*, 52 F.3d 1035, 1037, 34 USPQ2d 1467, 1468-69 (Fed. Cir. 1995); *Van Geuns*, 988 F.2d at 1186; *see also* PTO Notice of Final Rule, Patent Appeal and Interference Practice, 60 Fed. Reg. 14488, 14506, 1173 Off. Gaz. Pat. Office 36, 51 (1995) ("There is no presumption in an interference that because one claim designated to correspond to a count is unpatentable over the prior art (35 U.S.C. 102(a), (b) and (e)), that all claims are unpatentable over the same prior art."); 37 C.F.R. § 1.633(a) (1996) (requiring motions filed after April 21, 1995, to "separately address each claim alleged to be unpatentable"). However, where the party urging patentability does not separately address the patentability of each claim corresponding to a count, the Board has reason to treat all claims together. *See Van Geuns*, 988 F.2d at 1186. In such cases, all claims corresponding to the count stand or fall together. *See id.*; *see also In re King*, 801 F.2d 1324, 1325, 231 USPQ 136, 137 (Fed. Cir. 1986) (dependent claims stand or fall with independent claims unless argued separately).

[1] The administrative patent judge, the Board, and the parties did not track the claims in this case with precision. The interference involves Rowe's claims 53-66. Dror's initial motion sought a determination that Rowe's claims 53-55, 59-60, 62, and 64-66 were unpatentable over the prior art. The administrative patent judge, however, issued a show cause order pertaining to all Rowe's claims 53-66. *See* 37 C.F.R. § 1.640 (d)(1) (1996). In its appeal to the Board, Rowe pointed out that the administrative patent judge "incorrectly state[d]" the subject of Dror's motion, and appealed the prior art rejection only as to claims 53-55, 59-60, 62, 64-66. In spite of Rowe's objection, the Board treated claims 53-66 together. Because the administrative patent judge is authorized to raise *sua sponte* the patentability of any claim involved in the interference, 37 C.F.R. § 1.641, this apparent disconsonance in the record does not prevent this court from considering the validity of all of Rowe's claims 53-66. *See, e.g., Chester v. Miller*, 906 F.2d 1574, 1576, 15 USPQ2d 1333, 1335 (Fed. Cir. 1990) (examiner-in-chief issued a show cause order based, in part, on a party's motion and, in part, on examiner's own motion).

Because Rowe did not separately argue the patentability of his various claims before the administrative patent judge or the Board, this court need not treat those claims separately either.

This court reviews the Board's finding of anticipation as a question of fact subject to the clear error standard. *See id.* at 1326. "A finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *United States v. United States Gypsum Co.*, 333 U.S. 364, 395 (1948).

A prior art reference anticipates a claim only if the reference discloses, either expressly or inherently, every limitation of the claim. *See Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "[A]bsence from the reference of any claimed element negates anticipation." *Kloster Speedsteel AB v. Crucible, Inc.*, 793 F.2d 1565, 1571, 230 USPQ 81, 84 (Fed. Cir. 1986).

This appeal depends on whether the claim phrase "balloon *angioplasty* catheter," which appears only in the claim preamble, is or is not an affirmative limitation of the claim. The Board interpreted the claim as "drawn to the subject matter of a balloon catheter of general utility" and gave no meaning to the word "angioplasty." On this basis, the Board concluded that the Lemelson patent, which admittedly discloses only a general purpose catheter, anticipated Rowe's claims. Rowe urges that the Board erred in failing to limit the claims at issue to angioplasty catheters.

"[A] claim preamble has the import that the claim as a whole suggests for it." *Bell Communications Research, Inc. v. Vitalink Communications Corp.* 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). Where a patentee uses the claim preamble to recite structural limitations of his claimed invention, the PTO and courts give effect to that usage. *See id.*; *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989). Conversely, where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. *See Bell Communications*, 55 F.3d at 620; *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

The determination of whether preamble recitations are structural limitations or mere statements of purpose or use "can be resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Corning Glass Works*, 868 F.2d at 1257. The inquiry involves examination of the entire patent record to determine what invention the patentee intended to define and protect. *See Bell Communications*, 55 F.3d at 621 (looking to patent specification to determine whether claimed invention includes preamble recitations); *In re Paulsen*, 30 F.3d 1475, 1479, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) (examining "patent as a whole"); *Vaupel Textilmaschinen KG v. Meccanica Euro Italia SPA*, 944 F.2d 870, 880, 20 USPQ2d 1045, 1053 (Fed. Cir. 1991) (looking to claims, specification, and drawings); *Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 689, 16 USPQ2d 1436, 1441 (Fed. Cir. 1990) (noting that preamble recitations provided antecedent basis for terms used in body of claim); *Corning Glass Works*, 868 F.2d at 1257 (considering the specification's statement of the problem with the prior art); *Kropa*, 187 F.2d at 152 (noting that preamble sets out distinct relationship among remaining claim elements).

[1] Inspection of the entire record in this case reveals that "angioplasty" is, in fact, a structural limitation of Rowe's claims. To begin with, the form of the claim itself, the so-called "Jepson" form, suggests the structural importance of the recitations found in the preamble. The Jepson form allows a patentee to use the preamble to recite "elements or steps of the claimed invention which are conventional or known." 37 C.F.R. 1.75(e) (1996). When this form is employed, the claim preamble defines not only the context of the claimed invention, but also its scope. *See Pentec, Inc. v. Graphic Controls, Corp.*, 776 F.2d 309, 315, 227 USPQ 766, 770 (Fed. Cir. 1985) ("Although a preamble is impliedly admitted to be prior art when a Jepson claim is used, . . . the claimed invention consists of the preamble in combination with the improvement" (citations omitted); United States Patent and Trademark Office, *Manual of Patent Examining Procedure* § 608.01(m) (6th ed. rev. Sept. 1995) ("[The Jepson form of claim] is to be considered a combination claim. The preamble of this form of claim is considered to positively and clearly include all the elements or steps recited therein as a part of the claimed combination."). Thus, the form of the claim itself indicates Rowe's intention to use the preamble to define, in part, the structural elements of his claimed invention. The device for which the patent claims "an improvement" is a "balloon angioplasty catheter."

The court looks next to the specification and drawings to determine whether those sources convey a clear structural meaning for the phrase "balloon angioplasty catheter." The parties argue over whether this court should interpret the claim with reference to the Dror patent, in which it originated, or the Rowe application, into which it was copied. The nature of this inquiry provides the answer. At this juncture, this court and the PTO examine claims to determine their patentability over the prior art. In effect, section 1.633(a) allows the PTO to consider the novelty or non-obviousness of each application's claims as if the application stood alone. In this posture, the PTO properly interprets the claim in light of its host disclosure, just as it would during *ex parte* prosecution. Thus, this court looks to the Rowe application to determine the meaning of the phrase at issue.

[2] Notwithstanding Dror's arguments, this court's holding in *In re Spina*, 975 F.2d 854, 24 USPQ2d 1142 (Fed. Cir. 1992), does not apply to the present case. In *Spina*, this court considered whether an applicant was eligible to copy a patentee's claim and thereby challenge priority of invention, a question that turned on whether the copying party's specification adequately supported the subject matter claimed by the other party. *Id.* at 856. This court held, in that context, that a copied claim is interpreted in light of its originating disclosure. [2] *Id.* This *Spina* rule sought to ensure that the PTO would only declare an interference if both parties had a right to claim the same subject matter. However, that rule does not apply in cases, such as this one, where the issue is whether the claim is patentable to one or the other party in light of prior art. In this posture, the PTO and this court must interpret the claim in light of the specification in which it appears.

Without question, the Rowe specification evinces a particular and distinct structural meaning for "balloon angioplasty catheter" that distinguishes it from "balloon catheters" generally. In particular, an angioplasty catheter must be capable of "expand-[ing] a stenosis in a coronary artery." The specification repeatedly refers to "dilation of coronary arteries," "expanding the coronary artery," and other unique functions of "PCTA [percutaneous transluminal coronary angioplasty] catheters." Figures 2 through 4 illustrate the radial expansion of an area of stenosis by the forceful inflation of a balloon catheter. The specification also indicates that the pressure exerted against the vessel walls upon balloon inflation forces the medication into the stenosis. These and similar phrases limit the claimed "balloon angioplasty catheters" to catheters that can be inflated radially outward to dilate a narrowed region in a blood vessel.

Dror argues that Rowe's claim broadly includes all balloon catheters because Rowe's specification indicates that "[t]he invention of this application can be used in a wide variety of medical procedures above and beyond dilation of stenoses in coronary arteries." Rowe's specification also teaches the use of "catheters and flexible probes which do not carry a balloon" in non-angioplasty procedures as an alternative embodiment of Rowe's invention. Quite to the contrary of Dror's argument, these passages indicate that Rowe recognized a difference between angioplasty catheters and other types of catheters. Thus, when he uses the phrase "balloon *angioplasty* catheter" in his claim, it is that device, not some other, that he defines.

In concluding that "angioplasty" was not a structural limitation of the claim, the Board relied on claim language requiring that the microcapsules contain "a drug or combination of drugs for treatment or *diagnosis* within a body lumen" (emphasis added). According to the Board:

> Since a diagnostic procedure is completely different from expanding a stenosis, [Rowe's] argued narrow interpretation of the preamble directly conflicts with the broader literal language of the claim. Interpreting the invention as a whole, we agree with the APJ that the claim language should be interpreted as drawn to the subject matter of a balloon catheter of general utility.

Contrary to the Board's reasoning, the claim term "diagnosis" is consistent with limiting the claim to angioplasty apparatus. Indeed, Dror's specification provides an example of an angioplasty procedure being performed contemporaneously with a diagnostic procedure. Specifically, the specification expressly teaches the use of diagnostic agents, such as radiopaque dyes, in angioplasty procedures to "allow the vessel to be visualized."

During the patent examination process, claims receive their broadest reasonable meaning. *See In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). However, this does not relieve the PTO of its essential task of examining the entire patent disclosure to discern the meaning of claim words and phrases. *See, e.g., Paulsen*, 30 F.3d at 1479-80; *In re Bulloch*, 604 F.2d 1362, 1365, 203 USPQ 171, 174 (CCPA 1979) (looking to specification and record to discern what the applicant claimed).

Thus, when properly interpreted, Rowe's claims require a balloon angioplasty catheter capable of expanding radially and exerting pressure on the plaque-encrusted walls of a surrounding blood vessel. The Lemelson patent does not show such a catheter, but instead describes a general purpose balloon catheter. Lemelson describes a medicated swab that extends out the end or side of the catheter to allow contact with the internal surface in need of medication. Although the Lemelson patent does describe substitution of a balloon for the medicated swab, it does not illustrate this balloon embodiment. Thus, even an artisan of ordinary skill must guess about how exactly the balloon would substitute for the medicated swab and whether the resulting balloon catheter would be capable of radial, as well as axial, expansion. In fact, Lemelson makes no suggestion of any kind about its structural suitability for angioplasty procedures. About the most that can be said for the Lemelson patent is that it does not explicitly describe anything inconsistent with angioplasty procedures. However, this negative pregnant is not enough to show anticipation. *See In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) (in order to anticipate, "the [prior art] reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it").

[3] Although anticipation is a question of fact, *see In re Bond*, 910 F.2d 831, 833, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990), this court can conclude from this record that the Lemelson patent does not anticipate Rowe's properly interpreted claim. Neither the administrative patent judge nor the Board indicated that the Lemelson patent disclosed a "balloon angioplasty catheter." In fact, the Board would not have likely paid so much attention to whether Rowe's claim was limited to balloon angioplasty catheters if it had believed that the Lemelson patent showed such a catheter anyway. Further, the record does not show that Dror argued, either before the PTO or before this court, that the Lemelson patent discloses a "balloon angioplasty catheter." Dror's failure to deny Rowe's clear and forcible allegations is tantamount to an admission.

CONCLUSION

Because the Board clearly erred in its conclusion that the Lemelson patent anticipated Rowe's claims corresponding to the interference count, this court reverses. The case is remanded to the PTO for further proceedings in the interference.

COSTS

Each party shall bear its own costs.

REVERSED AND REMANDED.

[2] This court is aware of the PTO's 1995 amendment to 37 C.F.R. § 1.633 (a), which added a sentence: "In deciding an issue raised in a motion filed under this paragraph (a), a claim will be construed in light of the specification of the application or patent in which it appears." 37 C.F.R. § 1.633 (a) (1996) (effective date of amendment, April 21, 1995); *see also* 60 Fed. Reg. 14488, 14505, 1173 Off. Gaz. Pat. Office 36, 51 (1995) (explanatory notes on adoption of amended provision). This court does not accept the PTO's statement that it can "administratively set aside the judicially created rule of *In re Spina*," *see* 59 Fed. Reg. 50181, 50185, 1167 Off. Gaz. Pat. Office 98, 101 (1994). Judicial precedent is as binding on administrative agencies as are statutes. However, the PTO had good reason to promulgate a new rule in light of the new practice in which patentability of claims can be considered during the motion period of an interference. *See* 37 C.F.R. 1.633(a) (effective date February 11, 1985). Earlier case law did not deal with such a situation. Moreover, *Spina* did not involve a Rule 633(a) motion. Thus, the PTO was writing on a clean slate, not flouting judicial precedent.

U.S. Court of Appeals
Federal Circuit

Elkay Manufacturing Co. v. Ebco Manufacturing Co.

No. 94-1424

Decided October 29, 1996
(Unpublished)

PATENTS

1. Infringement — Defenses — License (§120.1102)

Federal district court erred in granting summary judgment that bottle cap with frangible connection, which is part of patented hygienic liquid dispensing system, has no non-infringing uses, and that plaintiff's action in licensing manufacture and sale of caps to third party therefore created implied license in defendant to practice invention of patent, since district court did not address questions of whether frangible cap can be useful principally for purpose of sealing water bottles during storage and transportation, and whether it would be reasonable from business perspective to use frangible cap in same manner as conventional caps, since

A person shall be entitled to a patent unless—

. . .

(b) the invention was patented or described in a printed publication in this or a foreign country *or in public use or on sale in this country, more than one year prior to the date of the application for patent* in the United States . . .

35 U.S.C. § 102 (emphasis added).[1]

The Federal Circuit has explained the purpose behind this statutory bar, indicating:

> Section 102(b), like its predecessors, refers to disclosure of the "invention." The purpose of the statute is to require the inventor to exercise diligence in filing his patent application, and to prevent him from extending the period of his limited patent grant by means of successive minor improvements, each arguably supporting a new claim on the original invention. In addition, it provides a fixed date, often more readily ascertainable than the date of the invention, for evaluating the significance of prior art and resolving issues of priority. The purposes of the statute would be largely frustrated if the limitation bar could be tolled by the development of improvements which, though novel, represent no advance over the basic conception.

Frantz Mfg. Co. v. Phenix Mfg. Co., 457 F.2d 314, 320 [173 USPQ 266] (7th Cir. 1972) (footnotes omitted).

Because of this, courts have rejected a strict uniformity test when deciding cases under § 102(b). *See id.*; *see also* 2 Chisum, *Chisum on Patents*, § 6.02[3][b], 6-31 (1997). Courts apply the same standard as they would to determine whether a patent has been infringed.

> "Once in public use, that invention becomes prior art and as to all later discoveries in that field anyone else must show some 'patentable' change to obtain the legal monopoly. Once the year in which to prepare and file this application has passed, the employment of a standard of patentability less stringent against the first inventor than against these others would seem to impair, if not defeat, congressional policy."

Frantz, 457 at 321 (quoting *Illinois Tool Works, Inc. v. Solo Cup Company, Inc.* [172 USPQ 385] (7th Cir. Jan. 26, 1972, No. 18960, p. 9)).

Further, in order to determine whether a design patent has been infringed, courts apply an ordinary observer test:

> "[I]f, in the eye of an ordinary observer, giving such attention as a purchaser usually gives, two designs are substantially the same, if the resemblance is such as to deceive such an observer, inducing him to purchase one supposing it to be the other, the first one patented is infringed by the other.

1 Chisum, *supra*, § 1.04[4], at 1-226.

The test to be applied is therefore whether the subject matter of the patents should have been obvious to a person having ordinary skill in the art at the time the prototype was used. *See id.* at 318-22.

[1] The Court finds that Soulbella has not carried its burden of showing likelihood of success on the merits as to the issue of prior use. Soulbella acknowledges that an easel was used at the 1993 Goldwell Coloration Seminars and has not provided any evidence that this use does not constitute a public use. Further, Soulbella has made no showing that the patents in question contain some "patentable" change from the easel displayed at the 1993 Goldwell Coloration Seminars such that the statutory bar does not apply.

The Court finds that because Soulbella has not made a showing of likelihood of success on the merits, the equities weigh against issuing a preliminary injunction.

Therefore, for the reasons stated above and for the reasons stated on the record at the August 3, 1998 hearing of Soulbella's motion for preliminary injunction, Soulbella's motion is denied.

IT IS SO ORDERED.

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[1] The party asserting this statutory bar has the initial burden of showing by clear and convincing evidence facts which support the existence of a public use within the meaning of the section. *See Tone Bros., Inc. v. Sysco Corp.*, 28 F.3d 1192, 1197 n.4 [31 USPQ2d 1472] (Fed. Cir. 1994). Once the party asserting the bar has established a prima facie case, the burden is shifted to the patent owner to come forward with convincing evidence to counter the challenger's showing. *See id.*

U.S. Court of Appeals Federal Circuit

ATD Corp. v. Lydall Inc.

Nos. 97-1308, -1356

Decided October 6, 1998

PATENTS

1. Patent construction — Claims — Defining terms (§125.1305)

Term "embossments," as used in claims of patents for thermal insulation pads, means depressions or bumps that separate and form gap between at least some of foil layers in pads by point contact of embossments with adjacent layers, since specifications show and claims require that insulating gap between at least some of metal foil layers in pad is formed by embossments that space apart foil layers, since presence of embossments making contact with adjacent layers of foil to separate layers is described in specifications as material aspect of invention, and since use of heat-resistant mesh or scrim between some layers, even without embossments, does not defeat requirement of even broadest claims that pad contain at least two layers of foil bearing embossments that separate those layers.

2. Infringement — Literal infringement (§120.05)

Federal district court properly granted summary judgment that accused thermal insulation does not literally infringe asserted claims of patents in suit, since claims require that at least two foil layers in insulation pads have "embossments" that separate and form gap between layers by point contact, since this separation function is express limitation of claims, and since, in accused product and method, there is no contact between impressed relief pattern on foil layers, which are separated by metal mesh, and any adjacent layer.

3. Infringement — Doctrine of equivalents — In general (§120.0701)

Substantial evidence supports jury's verdict that accused thermal insulation does not infringe asserted claims of patents in suit under doctrine of equivalents, since defendant presented expert testimony that metal mesh in accused product, which performs same function of separating foil layers of insulation pad as "embossments" of claims, does so in substantially different way to produce substantially different result, and that use of mesh preserves sheet reflectivity and results in greater crush resistance, providing advantages as well as differences.

4. Patentability/Validity — Anticipation — Identity of elements (§115.0704)

None of cited prior art references anticipate asserted claims of patents for thermal insulation, since none of them show combination of embossed insulating layers and compressed heat sink layers required by claims.

5. Patentability/Validity — Obviousness — Combining references (§115.0905)

Patentability/Validity — Obviousness — Secondary considerations generally (§115.0907)

Patents for thermal insulation are not obvious over combination of prior art references cited by infringement defendant, even though "embossments" similar in general shape to those of patents have been used to space insulating layers of various forms, since some references cautioned against compressing layers in multilayer insulator, and none showed compressing layers to form heat sink as in patented product and method, since there is no evidence of teaching or suggestion to select components inventors selected, from crowded field of insulation technology, to produce product and method of patents, and since patented product met unsolved need and was quickly adopted by automotive industry.

6. Practice and procedure in Patent and Trademark Office — Prosecution — Duty of candor — Citation of references (§110.0903.08)

Applicant did not engage in inequitable conduct by failing to cite prior art U.S. patent, or Patent Cooperation Treaty search report and prosecution records applying that patent to corresponding PCT application, in divisional application for patent in suit, since prior patent was cited in prosecution of parent application, and it is not inequitable conduct to fail to resubmit, in divisional application, information cited or submitted in parent, and since applicant was not required to resubmit documents relating to prior patent in record of PCT application when that patent was already of record in U.S. application; details of foreign prosecution are not additional category of material information.

JUDICIAL PRACTICE AND PROCEDURE

7. Procedure — New trial; JMOL (§410.30)

Standard to be applied in determining whether admission of evidence in patent

infringement action constituted harmless error is not whether there was "substantial evidence" of non-infringement without tainted evidence, since Fed.R.Civ.P. 61 defines harmless error as any error or defect in proceeding "which does not affect the substantial rights of parties"; admission of evidence is therefore reviewed for whether, under circumstances presented, it reasonably affected outcome of case.

8. Procedure — New trial; JMOL (§410.30)

Admission of infringement defendant's patent as evidence that its products were substantially different from and superior to that covered by plaintiff's patents, under circumstances in which plaintiff was unable to present defense on substance of defendant's patent, does not warrant new trial, since, in view of correctly construed claims, reasonable jury could not have found either literal infringement or infringement under doctrine of equivalents, and admission of defendant's patent as evidence therefore did not affect outcome of case.

9. Procedure — Discovery — In general (§410.4001)

35 USC 282, which provides that party asserting invalidity of patent in suit must give notice of prior art relied upon as evidence of anticipation to adverse party at least 30 days before trial, does not override discovery schedule set under Federal Rules of Civil Procedure, since procedure set by court and agreed to by parties necessarily governs particular trial, and although Section 282 sets minimum period for identification of prior art to be introduced as evidence of anticipation, specific judicial directive for timing of discovery establishes procedures to which parties are bound.

Particular patents — Chemical — Thermal insulation

5,011,743, Sheridan and Ragland, pad including heat sink and thermal insulation areas, judgment of non-infringement affirmed; judgment of invalidity reversed.

Particular patents — General and mechanical — Thermal insulation

5,111,577, Sheridan and Ragland, pad including heat sink and thermal insulation areas, judgment of non-infringement affirmed; judgment of invalidity reversed.

Appeal from the U.S. District court for the Eastern District of Michigan, Rosen, J.; 43 USPQ2d 1170.

Action by ATD Corp. against Lydall Inc. for patent infringement. Plaintiff appeals from judgment holding certain claims of patents in suit invalid and not infringed, and defendant cross-appeals from holding that inequitable conduct was not established. Affirmed in part and reversed in part; Clevenger, J., concurring in part and dissenting in part in separate opinion.

Bruce T. Wieder, Frederick G. Michaud Jr., Eric H. Weisblatt, and Ronni Jillions, of Burns, Doane, Swecker & Mathis, Alexandria, Va., for plaintiff-appellant.

Barry L. Grossman, of Foley & Lardner, Washington, D.C.; William P. Atkins, of Pillsbury, Madison & Sutro, Washington, for defendant-cross appellant.

Before Rich, Newman, and Clevenger, circuit judges.

Newman, J.

ATD Corporation appeals the final judgment [1] of the United States District Court for the Eastern District of Michigan, holding the claims in suit of United States Patents No. 5,011,743 (the '743 patent) and No. 5,111,577 (the '577 patent), both entitled "Pad Including Heat Sink and Thermal Insulation Areas," invalid and not infringed. We affirm the rulings of non-infringement and reverse the rulings of invalidity. On Lydall's cross-appeal we affirm that inequitable conduct was not established. The challenged evidentiary rulings are sustained.

BACKGROUND

The '743 patent relates to a flexible insulating pad that includes heat sink and thermal insulation areas. It is described as particularly useful for providing "hot spot" insulation, and is used primarily in automotive underbodies. It achieved prompt commercial acceptance, as an economical and efficient structure for dissipating heat. Two of the patent drawings are reproduced below. Fig. 1 a top view and Fig. 2 a cross section of the patented pad:

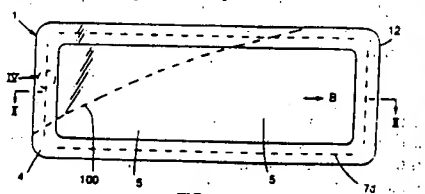

FIG. 1

[1] *ATD Corp. v. Lydall, Inc.*, 43 USPQ2d 1170 (E.D. Mich. 1997).

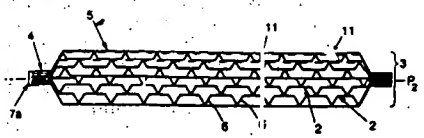

FIG. 2

The thermal insulation area *5* is made of layers of metal foil *2* separated by air gaps, and the heat sink area *4* is formed by compressing the edges of the foil layers. The depressions at *6* are called "embossments," and the dashed lines at *11* represent optional layers of heat-resistant scrim.

Claims 1 and 3 of the '743 patent are at issue, shown with emphases added to highlight the disputed subject matter with respect to infringement; all of the other claim elements and limitations are conceded to be present in the accused pads

1. A pad including thermal insulation and heat sink areas comprising:

a plurality of layers of metal foil forming a stack wherein said layers are arranged one above another in a vertical direction,

said stack including at least one heat sink area and at least one thermal insulating area adjacent to said heat sink area,

said layers providing better heat condition in said vertical direction at said heat sink area than at said insulating area,

at least two of said layers including *a plurality of embossments therein separating said layers in said insulating area so as to provide gaps therebetween,*

one of said layers in said insulating area being adjacent to and not metallurgically bonded to another one of said layers,

said heat sink area comprising a compressed portion of said stack.

3. The pad of claim 1, wherein said heat sink area at least partly surrounds said insulating area and said layers in said heat sink area are interengaged with each other by securing means.

The '577 patent is a division of the '743 patent, and relates to the manufacture of the pad. Claims 1, 11, and 19 of the '577 patent are as follows, with emphases added to show the usages of "embossments," the only point of dispute.

1. A method of making a heat insulating pad having insulating and heat sink areas, comprising:

a step of assembling a plurality of layers of metal foil in a stack wherein said layers are arranged one above another in a vertical direction, *at least two of said layers being separated from each other by a plurality of embossments* on at least one of said layers;

a step of compressing at least one portion of said stack such that heat sink and insulating areas are formed therein with said layers providing better heat conduction in said vertical direction at said heat sink area than at said insulating area,

said embossments in said insulating area separating said layers so as to provide a gap therebetween; and

a step of securing said layers together in said heat sink area, said securing step including interengaging said layers in said heat sink area with each other.

11. A method of making a heat insulating pad having insulating and heat sink areas, comprising:

a step of assembling a plurality of layers of metal foil in a stack wherein said layers are arranged one above another in a vertical direction, *at least two of said layers being separated from each other by a plurality of embossments* on at least one of said layers; and

a step of compressing at least one portion of said stack such that heat sink and insulating areas are formed therein with said layers providing better heat conduction in said vertical direction at said heat sink area than at said insulating area,

said embossments in said insulating area separating said layers so as to provide a gap therebetween.

19. The method of claim 11, wherein said assembling step comprises assembling a plurality of layers of metal foil which make said pad flexible.

The accused Lydall pads contain heat sink and insulating areas, in accordance with the claims, and are the same as the ATD pads except that the Lydall foil layers are separated by knitted or woven mesh instead of by depressions in the foil. ATD argues that due to compression forces applied during manufacture, the Lydall foil layers are "embossed" with the impressions of the intervening mesh. ATD states that these "embossments," along with the mesh reach to the adjacent layers of foil, and thus that the product and process claims are infringed, literally or in accordance with the doctrine of equivalents.

Upon ATD's suit for patent infringement, Lydall raised the defenses of non-infringement, invalidity, and unenforceability. On cross-motions for summary judgment, the district court granted Lydall's motion that there was not literal infringement and no willful infringement. The district court also granted ATD's motion that there was not inequitable conduct in the prosecution of the patents. The court ruled that there were genuine issues of material fact on the issue of infringement under the doctrine of equivalents and the issue of validity; these issues were tried to a jury. The jury found that Lydall did not infringe, under the doctrine of equivalents, claim 3 of the '743 patent, nor claims 1, 5-7, 11, or 19 of the '577 patent. The jury deadlocked on the issue of infringement by equivalents of claim 1 of the '743 patent. The jury also found that claims 1 and 3 of the '743 patent and claims 1, 11, and 19 of the '577 were invalid based on prior art. The district court entered judgment accordingly, and denied all post-trial motions. Each side appeals the rulings adverse to it.

I

LITERAL INFRINGEMENT

Determination of the issue of literal infringement involves the steps of first construing the claims, a matter of law assigned to the judge whether or not a jury trial has been demanded, and then applying the construed claims to the accused device, a factual determination performed by the jury. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976, 34 USPQ2d 1321, 1326 (Fed. Cir. 1995) (in banc), *aff'd*, 517 U.S. 370, 38 USPQ2d 1461 (1996). In this case, as often occurs, the question of literal infringement was resolved upon the court's construction of the claims. *See id.* at 999, 34 USPQ2d at 1346 (Newman, J., dissenting) ("Deciding the meaning of the words used in the patent is often dispositive of the question of infringement.") Thus a court may grant summary judgment when, upon construction of the claims and with all reasonable factual inferences drawn in favor of the non-movant, it is apparent that only one conclusion as to infringement could be reached by a reasonable jury. *See* Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986) (purpose of summary judgment is to avoid an unnecessary trial); *Multiform Desiccants Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1476, 45 USPQ2d 1429, 1431 (Fed. Cir. 1998) (affirming ruling that given correct claim construction no reasonable jury could find literal infringement). Claim construction is determined *de novo* on appeal, *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448, 1456, 46 USPQ2d 1169, 1174 (Fed. Cir. 1998) (in banc); *Markman*, 52 F.3d at 979, 34 USPQ2d at 1329, as is the correctness of the grant of summary judgment, *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 532, 41 USPQ2d 1001, 1007 (Fed. Cir. 1996).

A. *Claim Construction*

The claims of both the '577 and '543 patents recite layers of metal foil having "a plurality of embossments" that separate the layers and establish gaps of insulating air between the layers. Lydall's position is that its foil layers are not "embossed"; ATD argues that they are, and that the district court erred in its construction of this term, leading to error in the ensuing decisions of non-infringement.

The district court drew on the two patent specifications for the meaning of "embossments" as used in the claims. *See Slimfold Mfg. Co. v. Kinkead Industries, Inc.*, 810 F.2d 1113, 1116, 1 USPQ2d 1563, 1566 (Fed. Cir. 1987) (claims are understood in light of the specification of which they are a part). When "the specification explains and defines a term used in the claims, without ambiguity or incompleteness, there is no need to search further for the meaning of the term." *Multiform*, 133 F.3d at 1478, 45 USPQ2d at 1433. However, when such definition is challenged it is often appropriate, despite facial clarity and sufficiency of the specification and the prosecution history, to receive evidence of the meaning and usage of terms of art from persons experienced in the field of the invention. *See* Fed. R. Evid. 702-706.

The specifications of both patents in suit define the embossments as "depressions" and "bumps or projections," the numbers referring to Fig. 2 *supra*:

> The embossments *6* form depressions on one side of a respective one of the layers *2* and bumps or projections on an opposite side of the respective layer.

'743 patent, col. 7, lines 37-39; '577 patent, col. 7, lines 41-44. The district court observed that this definition is consistent with the dictionary definition of "emboss" as meaning to "raise in relief from a surface." ATD argues that this definition supports its position, since Lydall's foil layers have "bumps and indentations." ATD argues that there is no reason to believe that the inventor used the term differently from its dictionary meaning, leaving no ambiguity and thus no need for "claim construction." ATD states that the district court erred in law in construing "embossments" as also requiring that the bumps and indentations reach from layer to layer of the foil. Thus ATD argues that since the claims are not ambiguous, and since "embossments" has a clear meaning, it is incorrect to add to the definition of "embossments" the requirement that they also serve to separate the layers of metal foil by the depth of the embossments that contact the adjacent layer of foil.

The specifications teach that the embossments make point contact between the adjacent layers of foil:

> The pad 1 can include two layers *2* only one of which includes the embossments *6*. In a preferred embodiment, however, at least two of the layers adjacent to each other include a pattern of the embossments *6*, the layers being offset with respect to each other such that at least some of the embossments are not aligned in the vertical direction. With this arrangement, the layers 2 can be provided in point contact to minimize heat transfer therebetween in the vertical direction *A*.

'743 patent, col. 7, lines 9-17; '577 patent, col. 7, lines 13-21. The district court also reviewed the patent drawings, and correctly described them as showing "the embossments as being raised reliefs on the various layers such that the embossments come in direct point contact with adjacent layers (Figures 2 and 5 of the '743 and '577 patents.)" The court concluded that "embossments" as used in the claims require raised reliefs that separate adjacent layers of foil by point contact.

ATD states that the district court erroneously incorporated into the definition of "embossments" in the claims in suit the structural feature of "point contact" from non-asserted claim 11 of the '743 patent, which reads:

> 11. The pad of claim 1, wherein said pad is flexible and at least some of said embossments form depressions on one side of a respective one of said layers and bumps on an opposite side of said respective layer, *said embossments providing point contact between the layers*.

(Emphasis added.) ATD argues that point contact is described in the specification as simply a preferred embodiment, and is not a limitation to the claims that do not include it. ATD states that a definition of embossments without point contact is also supported by the description in the '743 and '577 specifications of an embodiment wherein layers of a heat-resistant mesh or scrim are interposed between foil layers. ATD states that since claim 1 is generic to the various embodiments shown in the specification, it was an error of law to restrict the broadest claim to the embodiment illustrated in Fig. 2 wherein the embossments are in point contact with adjacent foil layers.

Lydall responds that the mere fact that non-asserted claim 11 specifically states that the embossments are in point contact does not preclude the construction of claim 1 as requiring that the embossments separate the layers. Lydall points out that for the embodiment in which ATD uses mesh between some foil layers, the specification shows that at least some of the layers are separated by point contact of the embossments. Non-asserted dependent claim 14 of the '743 patent, which specifies one or more layers of scrim, also incorporates the claim 1 limitation of at least two "layers including a plurality of embossments therein separating said layers in said insulating area so as to provide gaps therebetween."

The separation of layers and ensuing provision of insulating gaps arise from the point contact. Thus we agree that the correct interpretation of the claims in suit is that, whether or not mesh is used between some of the foil layers, the embossments serve to separate at least some of the layers. The doctrine of claim differentiation can not broaden claims beyond the scope that is supported by the specification. *Multiform Desiccants*, 133 F.3d at 1480, 45 USPQ2d at 1434 ("claim differentiation can not broaden claims beyond their correct scope"); *Tandon Corp. v. United States Int'l Trade Comm'n*, 831 F.2d 1017, 1023, 4 USPQ2d 1283, 1288 (Fed. Cir. 1987) ("Whether or not claims differ from each other, one can not interpret a claim to be broader than what is contained in the specification and claims as filed.") The presumption that separate claims have different scope "is a guide, not a rigid rule." *Autogiro Co. of America v. United States*, 384 F.2d 391, 404, 155 USPQ 697, 708 (Ct. Cl. 1967).

ATD also argues that the district court improperly added a method limitation to the product claims when it interpreted the method claims as requiring the embossments to be made on the metal sheets before the assembly process. The district court held that "[t]he specifications make clear that the 'embossments' as contemplated under the patents are made on the metal sheets *prior to any assembly process*" (district court's emphasis), and that "the '577 patent is very clear on pre-assembly embossment." The

court cited the specification of the '577 patent:

> The method according to the invention can also include a step of embossing a plurality of the layers *2* such that a plurality of the embossments *6* are formed therein, the embossing step being performed by simultaneously embossing a plurality of overlapping sheets *2* of the metal foil, *each of the sheets after the embossing step comprising a respective one of the layers*. The embossments can be provided in a random or uniform repeated pattern. It is also within the scope of the invention to emboss each sheet separately. *The embossments can be provided by passing a single sheet or stack of sheets between a pair of rollers having the desired embossment pattern thereon.*

'577 patent, col. 8, lines 32-44 (district court's emphasis).

This aspect is relevant to both the product and the method claims, for it was not disputed that in the Lydall pad a pattern of impressions is produced on the metal foil after the foil is assembled into layers, by compression of the foil against the intervening mesh. The specifications make clear that the "embossments" of the '743 and '577 patents are "something more than 'impressions' on the surface of the foil layers which are merely 'incidental,' " in the district court's words. The claims require that the "embossments" be deep enough to separate the adjacent layers of foil; the product claims are not dependent on how the embossments are made, and were not construed otherwise.

[1] Upon plenary review we confirm the district court's claim construction. The '743 and '577 specifications show and the claims require that the insulating gap between at least some of the metal foil layers is formed by the embossments that space apart the foil layers. In the patent specifications the presence of embossments making contact with adjacent layers of foil to separate the layers is described as a material aspect of the invention. The use of a mesh or scrim between some of the layers, even without "embossments" in those layers, does not defeat the requirement of even the broadest claims that the pad contain at least two layers of foil bearing embossments that separate the layers. Claim 1 of the '743 patent, correctly interpreted, embraces generically the use of mesh between some of the foil layers, but also requires that embossments on some of the foil layers make contact with and separate adjacent foil layers. All of the claims of both patents require embossments that serve this function, and the specifications make clear that this is essential to the patented invention. We conclude, as did the district court, that "embossments" as used in the '743 and '577 patents means depressions or bumps that separate and form a gap between at least some of the foil layers by point contact of the embossments with adjacent layers. This definition applies to all the claims in suit.

B. *Application to Accused Devices*

We give plenary review to the district court's grant of Lydall's motion for summary judgment of non-infringement, reapplying the standard for summary adjudication as applied by the district court.

Lydall's original product (discontinued after June 1, 1995) included an outer layer of metal foil with a "decorative pattern" in relief. The ensuing product did not include this outer pattern in relief. The court found that these indentations "projected outward, only — i.e., they did not provide point contact with adjacent interior solid metal layers, nor did they provide gaps between the layers." The court held that although these outer layers were "embossed" in the ordinary usage of the word, they did not contain "embossments" within the meaning of that term in the patents. We agree that no reasonable jury could have found otherwise.

In the Lydall product the metal foil layers are each separated by an intervening layer of metal mesh. When the mesh is pressed between the foil layers during the assembly process, there is created a patterned impression of the mesh on the smooth metal foil sheets. Applying the claims as construed, the district court found that these impressions do not constitute "embossments" as that term is used in the ATD claims, and that the Lydall impressions are "merely incidental to the contact of the mesh with the surface of the metal layers." The district court found that in the Lydall product it is the mesh that separates the layers and creates the insulating gap, and not the embossed depressions that are formed in the metal foil where it is pressed against the mesh. The court found that there was no point contact between the Lydall layers, as required by the court's claim construction, for "[t]he metal mesh in fact prevents all contact between the adjacent metal sheet layers." The court concluded that because there were no embossments providing point contact, summary judgment of no literal infringement was appropriate because an essential limitation of the claims was absent from the accused structure and method.

ATD argues that the Lydall embossments literally meet the claims' requirement of embossments, not only in the plain meaning of "emboss," but also because the Lydall embossments contribute along with the mesh to the gaps between the foil layers. ATD stresses that point contact is not a limitation to the claims in suit, and that the presence of the wire mesh between the foil layers of the Lydall product does not avoid literal infringement because there are embossments on the Lydall foil layers. ATD also argues that the issue of whether the Lydall embossments contribute to the gap between the layers of foil presents a question of material fact that could not be summarily resolved against ATD, and requests trial of this question.

[2] It is not disputed that in the Lydall product and method there is no contact between the impressed relief pattern on the foil layers, and any adjacent layer. There are no "embossments," as we and the district court construe the term as used in the patents, to separate the foil layers. This separation function is an express limitation of the asserted claims. In view of its absence from the accused product and method, no reasonable jury could have found that the asserted claims are literally infringed by the Lydall product or method. *See Cole*, 102 F.3d at 532, 41 USPQ2d at 1007 (affirming summary ruling of non-infringement when "accused products do not literally meet all of the claim limitations"). Therefore, summary judgment of no literal infringement was properly granted.

II

INFRINGEMENT BY EQUIVALENTS

The question of infringement in terms of the doctrine of equivalents was given to the jury. The district court construed the term "embossments," in Jury Instruction No. 25, as follows:

> *25.* . . . You are instructed that embossments are purposefully created patterns directly formed on individual foil layers that produced depressions on one side of a respective layer and bumps or projections on the opposite side of the respective layer. The embossments create projections providing direct point contact with adjacent layers. The embossments must be large enough to separate the layers and provide gaps between the layers.

ATD argues that the district court incorrectly construed the claims, thereby distorting the jury's finding of non-infringement and providing an incorrect basis for the jury verdict. *See United States Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568, 41 USPQ2d 1225, 1236 (Fed. Cir. 1997) (reviewing whether jury verdict was in accordance with correct claim construction). As we have discussed, the district court's construction of the term "embossments" correctly included the requirement of point contact.

[3] On the issue of equivalency the jury was instructed as follows:

> *27.* . . . Under the doctrine of equivalents, you must find that there are insubstantial differences between the patent claims and the alleged infringing product or method of making the product. In this regard, you may consider whether the defendant's product or method performs (1) substantially the same function (2) in substantially the same way (3) to produce substantially the same result when compared to the plaintiff's patented product or method, even though they may differ in name, shape or form.
>
> An accused product or method does not infringe under the doctrine of equivalents if it performs the function and achieves the result in a substantially different way than the claimed invention.
>
> The doctrine of equivalents does not involve the application of a formula and is not an absolute to be considered in a vacuum. Rather, the question of whether one component of the allegedly infringing product or method is equivalent to an element in the patented claim is a factual matter. It requires you to consider the context of the entire claim. Your answer will depend upon the drawings and written description, the patent application history, the prior art and all the circumstances of this case.
>
> * * * *
>
> Other factors to be considered in determining infringement is the known interchangeability of the accused and claimed elements or other objective technological evidence demonstrating that the substitute nevertheless represents a change that one of ordinary skill in the art would have considered "insubstantial" at the time of infringement. Evidence of copying and evidence of "designing around" are also relevant to the question of infringement under the doctrine of equivalents.

The issue of infringement under the doctrine of equivalents was fully litigated. One of Lydall's expert witnesses testified that the Lydall mesh is substantially different from the ATD embossments. He testified that

although the Lydall mesh and the ATD embossments perform the function of separating the foil layers, they do so in substantially different ways, leading to substantially different results. According to Lydall's expert, the use of the Lydall mesh preserves sheet reflectivity and results in greater crush resistance, providing advantages as well as differences. ATD disputed this evidence and its significance, and stressed that Lydall used the combination of a heat sink and insulator, the most important part of the ATD invention. Reviewing the record, we conclude that there is substantial evidence to support the jury verdict that there is not infringement under the doctrine of equivalents.[2] That judgment is affirmed.

III

PATENT VALIDITY

The jury verdict was that claims 1 and 3 of the '743 patent and claims 1, 11, and 19 of the '577 patent were invalid based on prior art. The district court entered judgment accordingly.[3] The evidence is reviewed to ascertain whether the jury's express or implicit factual findings were supported by substantial evidence, and whether the legal conclusion represented by the verdict was adequately based on supported findings, accompanied by correct application of the law to the facts. *See Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 619, 225 USPQ 634, 636 (Fed. Cir. 1985) ("In reviewing a decision denying a motion for judgment notwithstanding the verdict, we do not approach the issues as if there had been no trial. We review the evidence as a whole, and ascertain whether the verdict is in accordance with law, and whether there was substantial evidence in support of the jury's verdict.") In so doing, we resolve any disputed facts and draw all reasonable factual inferences in favor of the jury verdict. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1235, 9 USPQ2d 1913, 1919 (Fed. Cir. 1989); *DMI, Inc. v. Deere & Co.*, 802 F.2d 421, 425, 231 USPQ 276, 278-79 (Fed. Cir. 1986).

Although the verdict form did not state the ground on which the jury relied, Lydall had raised grounds of both anticipation and obviousness, and the parties have argued both of these grounds on appeal.

Anticipation

A patent is invalid for anticipation when the same device or method, having all of the elements and limitations contained in the claims, is described in a single prior art reference. *Richardson*, 868 F.2d at 1236, 9 USPQ2d at 1920; *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 894, 221 USPQ 669, 673 (Fed. Cir. 1984). An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of the invention. *See In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990); *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 1566, 1567, 7 USPQ2d 1315, 1317 (Fed. Cir. 1988). Lydall relied on seven references, as follows:

The Collier U.K. Patent No. 126,780, entitled *Improvements in or connected with the Construction of Boxes or Cases or like objects and of the Floors, Roofs, Walls, Partitions or other Parts of Railway or other Vehicles or like objects*, was cited in the prosecution of the '743 patent. Collier, discussing insulation of railway cars, shows the use of embossed projections to separate metal layers for insulation, but does not describe foil layers and heat sink areas, as required by each of the claims.

The Meckenstock German utility model shows a heat shield for gas-exhausting parts of motor vehicles. Meckenstock describes the use of two sheet metal plates, at least one of them including projections to separate the plates, but shows no foil layers as required by each of the claims.

The ASTM (American Society for Testing Materials) Pub. C 667-80, entitled *Standard Recommended Practice for Prefabricated Reflective Insulation Systems for Equipment and Pipe Operating at Temperatures Above Ambient Air*, describes a rigid inner and outer case protecting embossed liners, which may be foil. The reference does not show compressed foil to form heat sink areas, as required by each of the claims, and cautions against such deformation of the liners.

[2] The concurring/dissenting opinion draws analogy to a case styled *Vehicular Technologies*. However, the cases are not the same. In the case at bar the function of the embossments separating the layers is stated in the claims, whereas in *Vehicular* the function of back-up is stated only in the descriptive text of the specification.

[3] Although we have affirmed the judgment of non-infringement we review the merits of the judgment of invalidity, in accordance with *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 98, 26 USPQ2d 1721, 1728 (1993).

The ASTM Pub. C 740-82 entitled *Standard Practice for Evacuated Reflective Insulation in Cryogenic Service*, describes an insulator made from multiple layers of metal foil, the foil layers having embossments that separate the layers and form air gaps between the layers. This reference does not show compressing the layers to form heat sinks, and cautions against compression of the layers. Neither of the two ASTM references shows compressed layers of foil creating heat sink areas accompanying the insulating areas.

The article by F.E. Swalley et al., entitled *Practical Problems in Design of High-Performance Multilayer Insulation System for Cryogenic Stages*, Advances in Cryogenic Engineering, Vol. 10 at 208 (1965), describes a multilayer insulation system for cryogenic stages, again showing projections to space the layers apart, but does not show compressed layers of foil creating heat sink areas.

The article by L.D. Stimpson et al., entitled *Predicting Spacecraft Multilayer Insulation Performance from Heat Transfer Measurements*, Heat Transmission Measurements in Thermal Insulations, ASTM STP 544 (1974), is directed to multilayer insulation blankets in spacecraft. It describes multilayered insulation as "a series of radiation shields with low-conductivity spacers." Lydall does not discuss the substance of the Stimpson article in its brief, and we agree with ATD that Stimpson does not disclose an insulating area together with a heat sink area.

Logan et al. U.S. Patent No. 4,489,852 describes a cooking utensil, such as a cookie sheet, "of a double walled construction providing an insulating layer or volume of air therebetween," but does not show a stack of foil layers as called for by the claims. The parties stipulated that Logan et al. "do not disclose every element of the claims of the ATD patents arranged as in the claims."

[4] None of these references meets the criteria of anticipation, for none show the combination of embossed insulating layers and compressed heat sink areas. There was not substantial evidence to support a verdict of invalidity based on anticipation.

Obviousness

Obviousness is a legal conclusion based on underlying facts of four general types, all of which must be considered by the trier of fact: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any objective indicia of nonobviousness. *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966); *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1270, 20 USPQ2d 1746, 1750 (Fed. Cir. 1991); *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1566-68, 1 USPQ2d 1593, 1595-97 (Fed. Cir. 1987).

Determination of obviousness can not be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention. There must be a teaching or suggestion within the prior art, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources of information, to select particular elements, and to combine them in the way they were combined by the inventor. *See Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., Inc.*, 21 F.3d 1068, 1072, 30 USPQ2d 1377, 1379 (Fed. Cir. 1994) ("When the patented invention is made by combining known components to achieve a new system, the prior art must provide a suggestion or motivation to make such a combination."); *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 935, 15 USPQ2d 1321, 1324 (Fed. Cir. 1990) (the prior art must suggest to one of ordinary skill in the art the desirability of the claimed composition); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985).

ATD argues that there was not substantial evidence to support a finding that the prior art contained a teaching or suggestion to combine selected portions of the prior art in order to create the patented structure or method. ATD argues that the jury must have improperly reasoned with the hindsight of ATD's successful accomplishment. Lydall relied on the same group of references as for anticipation. However, Lydall points to no evidence supporting the obviousness determination, other than the conclusory opinion of its expert witness.

[5] We observe that embossments, similar in general shape to those of the ATD patents, have been used to space insulating layers of various forms. However, some of the cited references cautioned against compressing the layers in a multilayer insulator, and none showed compressing the insulating layers to form a heat sink as in the patented device and method. Lydall does not direct us to any evidence of a teaching or suggestion to select the components that ATD's inventors selected, from the crowded field of insulation technology, to produce the product and method of the '743 and '577 patents. Lydall's wit-

nesses themselves expressed the view that such compression would be undesirable, providing cogent evidence that one of ordinary skill would not have deemed it obvious to compress the layers of an insulating device for heat sink purposes. Absent substantial evidence of such teaching or suggestion in the prior art or in the general knowledge of persons of ordinary skill in the field, there was not substantial evidence to support the jury's verdict of obviousness. It was undisputed that the product met an unsolved need and was quickly adopted by the automotive industry, this commercial success also weighing against obviousness.

Because there was not substantial evidence supporting the verdict on the ground of either anticipation or obviousness, the judgment of invalidity is reversed.

IV

INEQUITABLE CONDUCT

Determination that a patent applicant engaged in inequitable conduct before the Patent and Trademark Office requires, as threshold findings of fact, both that the applicant failed to disclose material information to the PTO, and that he intended thereby to mislead or deceive the patent examiner into granting the patent. Materiality of the non-disclosed information, and culpable intent, must be established by clear and convincing evidence. When these facts are established, the court will weigh the findings and their premises and decide, in the court's exercise of discretion, whether to hold the patent unenforceable. *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 872, 9 USPQ2d 1384, 1389 (Fed. Cir. 1988) (in banc). We review the district court's ruling on the ultimate issue of inequitable conduct on the standard of abuse of discretion, *Kingsdown*, 863 F.2d at 876, 9 USPQ2d at 1392, while review of the underlying facts is on the clearly erroneous standard, with due consideration of the burden to establish both materiality and intent to deceive by clear and convincing evidence.

The district court ruled on summary judgment that the '743 and '577 patents were not unenforceable for inequitable conduct. Lydall appeals this ruling, stating that there were disputed facts as to whether certain information was material to patentability, and therefore that the issue was not amenable to summary disposition. Although the premises of inequitable conduct require findings based on all the evidence, a procedure that may preclude summary determination, *see KangaROOS U.S.A., Inc. v. Caldor, Inc.*, 778 F.2d 1571, 1577, 228 USPQ 32, 35 (Fed. Cir. 1985), a motion for summary judgment may be granted when, drawing all reasonable factual inferences in favor of the non-movant, the evidence is such that the non-movant can not prevail.

Lydall argued that during prosecution of the '577 divisional application ATD withheld U.S. Patent No. 2,212,481 to Sendzimir, as well as a PCT search report and prosecution records applying Sendzimir to the corresponding PCT application. Lydall argues that this inequitable conduct in prosecuting the '577 patent "infects" the '743 parent patent, and that both patents should be held unenforceable.

[6] The Sendzimir patent was cited in the prosecution of the '743 patent. Thus the district court found that ATD's failure to provide the Sendzimir information during the prosecution of the '577 divisional patent was not clear and convincing evidence of intent to deceive, observing that in accordance with M.P.E.P. §609 (Rev. 14, Nov. 1992)[1] a reference is not required to be resubmitted in prosecuting a divisional application:

> *§609.* . . . the patent examiner will consider information cited or submitted to the Office in a parent application when examining a continuing application, and a list of the information need not be submitted in the continuing application unless applicant desires the information to be printed on the patent.

In view of §609 it can not be inequitable conduct for an applicant not to resubmit, in the divisional application, the information that was cited or submitted in the parent application. *See Transmatic, Inc. v. Gulton Industries, Inc.*, 849 F. Supp. 526, 31 USPQ2d 1225 (E.D. Mich. 1994), *aff'd in pertinent part, rev'd in part*, 53 F.3d 1270, 35 USPQ2d 1035 (Fed. Cir. 1995) (a material reference that is already of record in parent application need not be resubmitted by the applicant in a continuing application). Nor was ATD required to submit the documents relating to Sendzimir in the record of the PCT application, when Sendzimir was already of record in the United States parent application. Although international search reports may contain information material to patentability if they contain closer prior art than that which was before the United States

[1] Further elaboration of the rule was subsequently made. *See* M.P.E.P. §609 (Rev. 3, July 1997).

examiner, it is the reference itself, not the information generated in prosecuting foreign counterparts, that is material to prosecution in the United States. The details of foreign prosecution are not an additional category of material information. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180, 33 USPQ2d 1823, 1828 (Fed. Cir. 1995) (duty to cite material references arising in related foreign applications).

We discern no clear error in the district court's ruling that because the Sendzimir reference was of record in the parent '743 application, and because M.P.E.P. §609 states that the information need not be resubmitted, there was not clear and convincing evidence of material withholding with intent to deceive. The summary judgment of no inequitable conduct is affirmed.

V

EVIDENTIARY RULINGS

Evidentiary rulings, when appealable, are reviewed under the criteria of the regional circuit, unless the evidentiary issue is unique to patent law or litigation and thus would benefit from national uniformity. *See National Presto v. West Bend Co.*, 76 F.3d 1185, 1188 n.2, 37 USPQ2d 1685, 1686 n.2 (Fed. Cir. 1996) ("On procedural matters not unique to the areas that are exclusively assigned to the Federal Circuit, the law of the regional circuit shal be applied.")

The abuse of discretion standard is applied to review of evidentiary rulings in the Sixth Circuit, as it is generally in the federal system. *E.g., Schrand v. Federal Pacific Elec. Co.*, 851 F.2d 152, 156-57 (6th Cir. 1988) ("This court applies an abuse of discretion standard in reviewing decisions of a trial court on the admission of evidence.") In addition, Fed. R. Civ. P. 61 provides, "No error in either the admission or the exclusion of evidence . . . is ground for granting a new trial or for setting aside a verdict . . . unless refusal to take such action appears to the court inconsistent with substantial justice." *See Schrand*, 851 F.2d at 156-57. Thus evidentiary decisions are reviewed for abuse of discretion, and may be reversed only when that abuse has led to harmful error or the denial of substantial justice. *Cooley v. Carmike Cinemas, Inc.*, 25 F.3d 1325 (6th Cir. 1994).

A

ATD asserts that the district court abused its discretion in allowing Lydall to present Lydall's U.S. Patent No. 5,424,139 ("the Lydall patent") as evidence that its products were substantially different from and superior to that covered by ATD's patents, and that substantial justice requires a new trial. ATD states that Lydall, by its tactics, denied ATD adequate time to respond to this evidence.

During discovery, for each of the 19 claims of the Lydall patent ATD submitted a request for admission, asking Lydall to admit that "each accused Lydall shield is made in accordance with" that claim of the Lydall patent. Lydall's response, for each claim, was "Denied." Lydall retained that position for five months after the close of discovery. Twenty-nine days before the start of trial, Lydall changed its responses to "Denied, except as to shields made with twisted expanded metal mesh." Based on this tardy change in position ATD moved in limine to exclude evidence of the Lydall patent. The motion was denied on the first day of trial, the district court stating that Fed. R. Civ. P. 36 binds a party to an admission, but not to a denial.

Lydall presented its patent as showing that its products were deemed patentable by the Patent Office, despite citation of the ATD patents, and for the comparative data in the Lydall patent which showed superiority of the accused products over the ATD product. Lydall presented five witnesses on these issues, giving substance to ATD's complaint about the tactics of the deliberately tardy identification of this issue. ATD states that by this tactic it was denied reasonable time to investigate the patent and its data, depose Lydall's witnesses, and present contrary evidence. ATD states that it was surprised, ambushed, and severely prejudiced. *See Erskine v. Consolidated Rail Corp.*, 814 F.2d 266, 272 (6th Cir. 1987) ("One of the primary objectives of the discovery provisions embodied in the Federal Rules of Civil Procedure is elimination of surprise in civil trials.")

Lydall responds that the fact of separate patentability is admissible evidence, a thus that the district court acted within discretion in admitting it. As for the tardiness of the discovery response, Lydall states that it properly denied ATD's requests for admission five months earlier because "'each' accused product was not so made." Lydall states that it amended its answers consistent with Fed. R. Civ. P. 26(e).

ATD states that all of the accused Lydall products are within the Lydall patent claims, but for a few prototypes. Lydall does not dispute this point. Nor does Lydall cite a change in circumstance justifying the

change in its interrogatory responses. Fed. R. Civ. P. 36 requires that "[a] denial shall fairly meet the substance of the requested admission, and when good faith requires that a party qualify an answer or deny only part of the matter . . . , the party shall specify so much of it as is true and qualify or deny the remainder." At the trial Lydall presented five witnesses on various aspects of its patent, its prosecution, and its comparisons with the ATD product. It is not reasonable to assume that Lydall planned this trial presentation within the twenty-nine days after it gave notice to ATD that it would rely on the patent. By no stretch of the Rules can Lydall or its counsel be deemed to have met reasonable standards of fairness, good faith, or professionalism.

[7] The district court, in its opinion denying ATD's request for a new trial, stated that even if there were error in admitting the evidence, it was harmless because there was substantial evidence supporting a verdict of non-infringement even without the evidence of the Lydall patent:

> Even if Lydall's patent were erroneously admitted, such an error was harmless. An error in the admission of evidence is not a ground for granting a new trial where the admission of the evidence was harmless error. Fed. R. Civ. P. 61. In this case, Lydall presented substantial evidence at trial of its effort to design around ATD's patents and also presented substantial evidence which showed that Lydall's metal mesh separated layers in a different manner than ATD's embossments. This evidence would support a non-infringement verdict even without evidence of Lydall's '139 patent.

That is not the correct standard. The question is not whether there was "substantial evidence" of non-infringement without the tainted evidence. *See* 11 Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure §2806 at 65 (1984 & Supp. 1998) ("[O]n a motion for a new trial . . . the judge may set aside the verdict even though there is substantial evidence to support it.") The question is whether the admission of the Lydall patent affected the substantial rights of ATD, *see* Fed. R. Civ. P. 61; Fed. R. Evid. 103, or was indeed harmless error. *See Schrand*, 851 F.2d at 157. Rule 61 provides:

> *Harmless Error.* No error in either the admission or the exclusion of evidence . . . is ground for granting a new trial or for setting aside a verdict . . . unless refusal to take such action appears to the court inconsistent with substantial justice. The court . . . must disregard any error or defect in the proceeding which does not affect the substantial rights of parties.

See also Fed. R. Civ. P. 59; 11 Wright & Miller, *supra* §2805 at 60 ("The importance of Rule 61 in its application to motions for a new trial cannot be overlooked. . . . [I]t is only those errors that have caused substantial harm to the losing party that justify a new trial. Those errors that are not prejudicial do not call for relief under Rule 59.") Therefore, we review whether the admission of this evidence, under the circumstances of the tardy discovery response, reasonably affected the outcome of the case. *See Schrand*, 851 F.2d at 157 (citing Fed. R. Civ. P. 61 and quoting *Jordan v. Medley*, 711 F.2d 211 (D.C. Cir. 1983) (Scalia, J.) ("assessment of the likelihood that the error affected the outcome of the case")); 1 Jack B. Weinstein & Margaret A. Berger, Federal Evidence §103.41[2] (1998) ("In general terms, the test of whether a substantial right of a party has been affected is whether the error in question affected the outcome of the case.")

Circuit Courts in civil cases not involving constitutional error have articulated the standard in different ways, *e.g.*, whether it is "highly probable" that the erroneous admission did not affect the jury verdict, 1 Weinstein & Berger, *supra* §103.41[2] at 103-53 n.32 (citing First, Third, and Eleventh Circuit cases); and whether it is "more probable than not" that the erroneous admission did not affect the jury verdict, 1 Weinstein & Berger, *supra* §103.41[2] at 103-53 n.33 (citing Seventh, Eighth, Ninth, and Tenth Circuit cases). *See also* 3 James Wm. Moore, Federal Practice §61.02[3] (1998) (standard of Rule 61 articulated in different ways). A number of factors have guided the courts in their determinations of whether error is harmless, including (1) whether erroneously admitted evidence was the primary evidence relied upon, (2) whether the aggrieved party was nonetheless able to present the substance of its claim, (3) the existence and usefulness of curative jury instructions, (4) the extent of jury argument based on tainted evidence, (5) whether erroneously admitted evidence was merely cumulative, and (6) whether other evidence was overwhelming. *See* 1 Weinstein & Berger, *supra* §103.41[5][a]-[h]; *see also* 11 Wright & Miller, *supra* §2885 [Rule 61] at 464 ("erroneous admission of evidence may be found not to have been prejudicial if the fact already had been shown by admissible evidence, or prejudice may be avoided by a curative instruction").

The district court noted that it gave a limiting instruction to the jury concerning the Lydall patent:

> 23. Where there is an issued patent, the later issuance of a patent for a device or method raises no presumption of noninfringement of the previously issued patent. You may consider the later issued Lydall patent in your decision and give it the appropriate weight, but you must keep in mind that even where improvements and modifications are separately patentable, the improved device or method may still infringe the previously issued ATD patents.
>
> A later patented device or method may include additional elements or steps beyond those claimed in the earlier issued patent. But if the later patented device or method contains each and every element of a claim of the earlier issued patent, or an equivalent of any element not literally included, then that claim of the earlier issued patent is infringed.

This instruction, however did not relate to ATD's asserted inability to present a defense on the substance of the Lydall patent.

[8] Following a careful review of the trial record, we do not grant ATD's request for a new trial. Considering ATD's emphasis on the use of embossed foil layers to separate the layers, and the use of metal scrim in both the prior art and between one or two of the ATD outer layers in addition to the embossments, we are convinced that in view of the correctly construed claims, a reasonable jury could not have found either literal infringement or infringement under the doctrine of equivalents. On this basis the admission of the Lydall patent did not affect the outcome of this case.

B

Lydall cross-appeals the district court's refusal to allow Lydall to present U.S. Patent No. 2,037,813 (the Munters patent) as evidence of invalidity of ATD's patents. The court excluded the Munters patent because Lydall did not produce the reference during the designated discovery period.

According to the record on December 20, 1994 ATD asked Lydall to identify each document Lydall considered to relate to validity and invalidity of the ATD patents. Lydall did not list the Munters patent in its reply of January 20, 1995. Subsequently, ATD served additional interrogatories and document requests, asking Lydall to identify prior art of which it was aware. Lydall did not list the Munters patent in any response. Following an extension, discovery closed on August 31, 1995. On December 1, 1995, Lydall served ATD with a "Notice of Prior Art Pursuant to 35 U.S.C. §282" listing the Munters patent. This was one month before a first rescheduled pretrial conference. Rejecting the submission, the court explained:

> I want the record to be clear as to the basis that I am denying Lydall the opportunity to use that prior art at trial. The basis is not relevance. The basis is not any evidentiary ruling as to the value of this prior art. The basis is simply I'm exercising my discretion under the rule of the Federal Rules of Civil Procedure to preclude a party from relying on theories not made available or not disclosed to the opposing side.

Lydall states that although the Munters patent was not disclosed in response to any of the discovery requests or during the discovery period, it should not have been excluded because it was disclosed in accordance with 35 U.S.C. §282:

> *§282.* . . . In actions involving the validity or infringement of a patent, the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as anticipation of the patent in suit . . . . In the absence of such notice proof of said matters may not be made at the trial except on such terms as the court requires.
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> . . .

Lydall argues that §282 overrides any discovery schedule set under the Federal Rules of Civil Procedure, because these Rules were instituted in 1938 whereas §282 was reenacted as part of the 1952 Patent Act. P.J. Federico, commenting on the 1952 Patent Act, reported the relationship in broad, and ambiguous terms:

> The last paragraph of section 282 relating to the giving of notice of various details relating to certain defenses is based on part of the last paragraph of old R.S. 4920, with modifications. The old provision was in fact superseded by the Federal Rules of Civil Procedure [28 U.S.C.A.] but, as modified, has been reinstated.

[9] P.J. Federico, *Commentary on the New Patent Act* (1954), *reprinted in* 75 J. Pat. Trademark Off. Soc'y 161, 216 (1993). Since 1952, the matter has not been squarely resolved. In *Thermo King Corp. v. White's Trucking Serv., Inc.*, 292 F.2d 668, 674, 130 USPQ 90, 94 (5th Cir. 1961), that court

referred to §282 as "coexisting" with the Federal Rules. We agree that they coexist. However, when the court has set and the parties have agreed to a discovery period, that procedure necessarily governs that trial. Thus although §282 sets a minimum period for the identification of prior art to be introduced as evidence of anticipation, a specific judicial directive for the timing of discovery establishes the procedures to which the parties are bound.

In *Eaton Corp. v. Appliance Valves Corp.*, 790 F.2d 874, 229 USPQ 668 (Fed. Cir. 1986) this court held that the trial court could, in its discretion, allow into evidence a reference that was not disclosed at least thirty days in advance despite §282, for in that case it was clear that the patentee was not surprised and was not prejudiced:

> The objective of section 282's provision for advance notice is to prevent unfair and prejudicial surprise by the production of unexpected and unprepared-for prior art references at trial. To this end, section 282 is to be read with the Federal Rules of Civil Procedure.

790 F.2d at 879, 229 USPQ at 672 (citations omitted). The purpose of §282, like that of the Federal Rules, is to prevent unfair and prejudicial surprise, not to facilitate last-minute production of evidence. The district court in the instant case was well within its discretion in excluding the Munters patent, for the record shows that Lydall offered no reason to justify its submission long after the close of discovery. The solid entrenchment of the Federal Rules and the principles of orderly discovery weigh heavily against Lydall's argument that §282 governs the requirement of notice of prior art despite the elaborate discovery procedures, interrogatories, and explicit directives by which the trial was managed.

Costs

Costs are taxed against Lydall. *See* Fed. R. App. P. 39; Fed. Cir. R. 39.

AFFIRMED-IN-PART and REVERSED-IN-PART.

Clevenger, J., concurring in part and dissenting in part.

I agree with the conclusions that the claims in suit are not infringed, either literally or by equivalents, and are not invalid for anticipation or obviousness. I also agree that the claims in suit are not unenforceable for inequitable conduct, and that no error infects the challenged evidentiary rulings. I write separately to indicate a few points of disagreement as to the path followed by the court to the conclusions, and to highlight the point that the claim interpretation, with which I agree, drives both of the infringement conclusions.

There is no infringement in this case because the accused devices lack embossments that make contact with and separate adjacent foil layers. The claims recite "embossments therein separating said layers . . . ." The claim language itself does not speak of point contact. Separation by point contact, as the court's opinion amply demonstrates, is emphasized in the written description. The claim term "embossments" is thus properly understood to require the function of separation by point contact.

The claim interpretation analysis in this case follows from our recent decision in *Vehicular Technologies Corp. v. Titan Wheel Int'l, Inc.*, 141 F.3d 1084, 46 USPQ2d 1237 (Fed. Cir. 1998). In that case, the key claim language called for two concentric springs in a spring assembly, and the written description clearly required that the second spring have a back-up spring function. We held in *Vehicular Technologies* that the back-up function of the second spring affects the range of equivalents available to the patentee. *Id.* at 1091. So it is in this case, as well. Here, the same claim interpretation analysis requires the embossments to function by point contact, a claim requirement that likewise affects the range of equivalents. Because of this analysis, no reasonable juror could find infringement of claim 1 of the '743 patent under the doctrine of equivalents. As the court notes, the jury deadlocked on that infringement question. The issue was preserved below by post-verdict motions for judgment as a matter of law, and ATD preserves the issue on appeal by challenging the denial of its motion for a new trial on the question of infringement by equivalents.

We need not remand the deadlocked equivalents issue, however, because the claim as interpreted requires point contact to achieve separation of the layers. A claim of infringement by equivalents cannot succeed unless each limitation of a claim is met by an equivalent. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 41 USPQ2d 1865 (1997) (adopting sub silentio the "all elements" rule of *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 225 USPQ2d 552 (Fed. Cir. 1987) (*in banc*)). Because the accused devices lack any equivalent to the function of point contact, they cannot infringe claim 1 as a matter of law. *See Vehicular Technologies* 141 F.3d at 1090.

With regard to the issue of inequitable conduct, the district court made no explicit ruling on the materiality of the allegedly nondisclosed matter. *ATD Corp. v Lydall, Inc.*, No. 94-CV-74320, slip op. at 43-46 (E.D. Mich. Jan. 9, 1995) (Opinion and Order Regarding Motions for Summary Judgment). Instead, the district court hinged its decision on the absence of proof of the requisite intent to deceive. *Id.* I thus would not dwell on the issue of materiality, as does the court, but instead would simply affirm the district court decision on its stated ground.

I disagree with the court's view that the district court applied an incorrect standard to test the new trial motion. In the opinion and order denying the Rule 59 motion, the trial court set out the same law that this court states is governing. *Compare ATD Corp. v. Lydall, Inc.*, 43 USPQ2d 1170, 1173, 1997 WL 11178.3, *3 (E.D. Mich. 1997) *with* the Maj. Op. at 29-30. The trial court then applied that "correct" law and determined that the alleged improper admission of Lydall's patent did not affect the substantial rights of ATD, because sufficient other evidence was before the jury to sustain its verdict of noninfringement by equivalents. *ATD Corp.*, 43 USPQ2d at 1173-79. In a footnote at the end of the discussion of the issue, the district court's opinion merely comments that even if there had been error in admitting Lydall's patent, the error would have been harmless. *Id.* at 1175 n.6. That comment is unrelated to the correct legal standard that the district court used to decide the Rule 59 motion, and cannot form a predicate for criticism of the district court.

Finally, I do not join the decision to tax costs to Lydall. Although the court speaks harshly of Lydall's conduct at trial, redress for trial court conduct properly lies in the trial court, not here. I am unaware of any reason to impose costs on Lydall.

U.S. District Court
Northern District of California

CyberMedia Inc. v. Symantec Corp.
No. C-98-20113-JF (EAI)
Decided September 4, 1998

COPYRIGHTS

1. Rights in copyright; infringement — Ownership of copyright — Transfer and licensing (§213.0310)

Transferee of copyright lacks good faith, for purposes of California's Uniform Fraudulent Transfers Act, Cal. Civ. Code §3439.08, if transferee colludes with debtor or otherwise actively participates in debtor's fraudulent scheme, or has actual knowledge of facts which would suggest to reasonable person that transfer was fraudulent.

2. Rights in copyright; infringement — Ownership of copyright — Transfer and licensing (§213.0310)

Infringement defendants have failed to show that plaintiff, in acquiring copyright at issue, was party to fraudulent transfer, since plaintiff's mere knowledge of existence of creditors with claims against transferor is not sufficient to show that transferee had intent to defraud these creditors, and since record does not support defendants' contention that $10.6 million was inadequate purchase price for software.

3. Rights in copyright; infringement — Right to reproduction — Access, copying, and substantial similarity — Works similar (§213.0503.03)

Plaintiff has demonstrated likelihood of success on merits of claim for infringement of copyrighted computer software, since portions of codes of parties' programs are strikingly similar, since common authorship, functional constraints, and common use of programming tools cannot explain why so many lines of code are identical or nearly identical, even to extent of containing common typographical error, and since code lines in question, although comprising relatively small percentage of program as whole, are essential to functioning of program.

REMEDIES

4. Non-monetary and injunctive — Equitable relief — Preliminary injunctions — Copyrights (§505.0707.04)

Recall of all infringing computer software products is only effective remedy in action for infringement of copyrights in software even assuming defendants' innocent intent and considering potential harm to public, since absent recall order, thousands of infringing products will continue to be sold in direct competition with plaintiff's product, thereby depriving plaintiff of customers it might otherwise have acquired, and since failure to order recall could lead to multiplicity of actions by plaintiff against distributors of infringing software; although international version of infringing software is manufactured overseas, injunction will apply only to infringing activity within United States.